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Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

**on the harmonisation of the laws of the Member States relating to making available on
the market of pressure equipment**

(Recast)

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

General context, reasons for and objectives of this proposal

This proposal intends to align Directive 97/23/EC on pressure equipment to the ‘goods package’ adopted in 2008 and in particular to Decision No 768/2008/EC establishing a common framework for the marketing of products. It also intends to align Directive 97/23/EC to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures¹.

a) Alignment to Decision No 768/2008/EC:

Union (EU) harmonisation legislation ensuring the free movement of products has contributed considerably to the completion and operation of the Single Market. It is based on a high level of protection and provides economic operators with the means to demonstrate conformity, thus ensuring free movement through trust in the products.

Directive 97/23/EC is an example of that Union harmonisation legislation, ensuring the free movement of pressure equipment. It sets out essential safety requirements that pressure equipment and assemblies must comply with in order to be made available on the EU market. Manufacturers must demonstrate that pressure equipment has been designed and manufactured in compliance with the essential safety requirements and affix the CE marking.

Experience with the implementation of Union harmonisation legislation has shown – on a cross-sector scale - certain weaknesses and inconsistencies in the implementation and enforcement of this legislation, leading to:

- the presence of non-compliant or dangerous products on the market and consequently a certain lack of trust in CE marking;
- competitive disadvantages for economic operators complying with the legislation as opposed to those circumventing the rules;
- unequal treatment in the case of non-compliant products and distortion of competition amongst economic operators due to different enforcement practices;
- differing practices in the designation of conformity assessment bodies by national authorities;
- problems with the quality of certain notified bodies.

Furthermore the regulatory environment has become more and more complex, as frequently several pieces of legislation apply simultaneously to one and the same product. Inconsistencies in these pieces of legislation make it increasingly difficult for economic operators and authorities to correctly interpret and apply that legislation.

¹ OJ L 353, 31.12.2008, p.1.

To remedy these horizontal shortcomings in Union harmonisation legislation observed across several industrial sectors, the ‘New Legislative Framework’ was adopted in 2008 as part of the goods package. Its objective is to strengthen and complete the existing rules and to improve practical aspects of their application and enforcement. The New Legislative Framework (NLF) consists of two complementary instruments, Regulation (EC) No 765/2008 on accreditation and market surveillance and Decision No 768/2008/EC establishing a common framework for the marketing of products (hereinafter NLF Decision).

The NLF Regulation has introduced rules on accreditation (a tool for the evaluation of competence of conformity assessment bodies) and requirements for the organisation and performance of market surveillance and controls of products from third countries. Since 1 January 2010 these rules apply directly in all Member States.

The NLF Decision sets out a common framework for EU product harmonisation legislation. This framework consists of the provisions which are commonly used in EU product legislation (e.g. definitions, obligations of economic operators, notified bodies, safeguard mechanisms, etc.). These common provisions have been reinforced to ensure that the directives can be applied and enforced more effectively in practice. New elements, such as obligations on importers, have been introduced, which are crucial for improving the safety of products on the market.

The provisions of the NLF Decision and those of the NLF Regulation are complementary and closely interlinked. The NLF Decision contains the corresponding obligations for economic operators and notified bodies allowing market surveillance authorities and authorities responsible for notified bodies to properly perform the tasks imposed on them by the NLF Regulation and to ensure an effective and consistent enforcement of EU product legislation.

However, unlike the NLF Regulation, the provisions of the NLF Decision are not directly applicable. To ensure that all economic sectors subject to Union harmonisation legislation benefit from the improvements of the NLF, the provisions of the NLF Decision need to be integrated into the existing product legislation.

The Commission has already proposed the alignment of nine other Directives to the NLF Decision within an NLF implementation package adopted on 21 November 2011².

² The ‘New Legislative Framework (NLF) Alignment Package’ of 21 November 2011 consisted of the following nine legislative proposals : Proposal for a Directive of the European Parliament and of the Council on the harmonisation of the laws of the Member States relating to the making available on the market of pyrotechnic articles (COM(2011) 764 final); Proposal for a Directive of the European Parliament and of the Council on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (COM(2011) 765 final); Proposal for a Directive of the European Parliament and of the Council on the harmonisation of the laws of the Member States relating to making available on the market of non-automatic weighing instruments (COM(2011) 766 final); Proposal for a Directive of the European Parliament and of the Council on the harmonisation of the laws of the Member States relating to making available on the market of simple pressure vessels (COM(2011) 768 final); Proposal for a Directive of the European Parliament and of the Council on the harmonisation of the laws of the Member States relating to making available on the market of measuring instruments (COM(2011) 769 final); Proposal for a Directive of the European Parliament and of the Council on the harmonisation of the laws of the Member States relating to making available on the market of lifts and safety components for lifts (COM(2011) 770 final); Proposal for a Directive of the European Parliament and of the Council on the harmonisation of the laws of the Member States relating to the making available on the market and supervisions of explosives for civil uses (COM(2011) 771 final); Proposal for a Directive of the European Parliament and of the Council on the harmonisation of the laws of the

In view of ensuring consistency across Union harmonisation legislation for industrial products, it is necessary to align Directive 97/23/EC to the provisions of the NLF Decision.

The proposal also takes into account the proposal of the Commission of 13 February 2013 for a Regulation on market surveillance of products³.

b) Alignment to Regulation (EC) No 1272/2008:

Regulation (EC) No 1272/2008 (hereinafter CLP Regulation), implements within the Union the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) that has been adopted at the international level, within the structure of the United Nations.

Directive 97/23/EC provides, in Article 9, for a classification of pressure equipment in categories, according to the ascending level of risk due to pressure. While the classification of pressure equipment under the Directive is mainly based on the total energetic content (pressure and volume of the pressure equipment), it is also influenced by the classification (dangerous or not) of the fluid it contains.

The classification of pressure equipment into categories is directly related to the conformity assessment procedure applied in order to verify the conformity of the pressure equipment to the essential requirements of Directive 97/23/EC. In particular, the conformity assessment procedure to be applied is determined by the category, as defined in Article 9, in which the equipment is classified.

The classification of the fluids contained in the pressure equipment for the purposes of the classification of the pressure equipment in view of its conformity assessment, is based on Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances⁴.

According to Article 9 of Directive 97/23/EC, the ‘fluids’ are divided into two groups. Group 1 comprises the following ‘dangerous fluids’⁵, as classified on the basis of their intrinsic properties and the degree and specific nature of the hazards involved in Directive 67/548/EEC: explosive, extremely flammable, highly flammable, flammable, very toxic, toxic and oxidising. Group 2 comprises all other fluids not referred to in Directive 97/23/EC as ‘dangerous’.

Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (COM(2011) 772 final); Proposal for a Directive of the European Parliament and of the Council on the harmonisation of the laws of Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits (COM(2011)773 final).

³ Proposal for a Regulation of the European Parliament and of the Council on market surveillance of products and amending Council Directives 89/686/EEC and 93/15/EEC, and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 1999/5/EC, 2000/9/EC, 2000/14/EC, 2001/95/EC, 2004/108/EC, 2006/42/EC, 2006/95/EC, 2007/23/EC, 2008/57/EC, 2009/48/EC, 2009/105/EC, 2009/142/EC, 2011/65/EU, Regulation (EU) No 302/2011, Regulation (EC) No 764/2008 and Regulation (EC) No 765/2008 of the European Parliament and of the Council. COM(2013) 75 final.

⁴ OJ 196, 16.8.1967, p.1.

⁵ According to Article 9 of Directive 97/23/EC, ‘a dangerous fluid is a substance or preparation covered by the definitions in Article 2(2) of Council Directive 67/548/EEC’.

To take account of the pressure hazards associated with dangerous fluids, the conformity assessment requirements of Directive 97/23/EC are more stringent for pressure equipment containing Group 1 fluids than for pressure equipment containing Group 2 fluids.

According to Regulation (EC) No 1272/2008, Directive 67/548/EEC will be repealed on 1 June 2015 and replaced by the Regulation. That Regulation introduces new hazard classes and categories only partially corresponding to those used under the current provisions.

The fluid classification criteria of Directive 97/23/EC must therefore be aligned to the classification criteria of Regulation (EC) No 1272/2008 until 1 June 2015, while maintaining the existing levels of protection of the Directive.

The alignment of Directive 97/23/EC to the CLP Regulation requires therefore redefining what constitutes a ‘dangerous fluid’ in the terms of the new classification introduced by the Regulation.

The need to align the fluid classification criteria of Directive 97/23/EC to the CLP Regulation is therefore a direct consequence of implementing the CLP Regulation in the Union, which requires all downstream legislation to be aligned to the CLP Regulation at the latest by the date on which Directive 67/548/EEC will be repealed (1 June 2015).

Although the two classification systems provided by the CLP Regulation and Directive 67/548/EEC are similar, there is no perfect match. Some substances are classified differently under the CLP Regulation than under Directive 67/548/EEC due to changes in the classification criteria or cut-off values. A change in the classification of the fluid (substance or preparation) contained in the pressure equipment may therefore result in a change of the classification of the pressure equipment itself (categories of pressure equipment).

Directive 97/23/EC provides for four categories of pressure equipment, according to the ascending pressure related hazard. For each category of pressure equipment, the Directive provides for a set of conformity assessment procedures. Pressure equipment must be subject to one of the conformity assessment procedures which may be chosen by the manufacturer among those laid down for the category in which the pressure equipment is classified. The manufacturer may also choose to apply one of the procedures which apply to a higher category, if available.

The change in category under Directive 97/23/EC is having an impact only on the conformity assessment procedure and not on the design or manufacturing of the pressure equipment itself. If pressure equipment is classified in a higher category due to the fluid it contains, it may result in a more demanding and more expensive conformity assessment procedure.

As the current provision⁶ related to the classification of pressure equipment based also on the characteristics of the fluid it contains is considered satisfactory, Directive 97/23/EC should be aligned to the CLP Regulation while maintaining the current scope in relation to the hazards due to the fluids. The new classification of the fluids should therefore match as close as possible the current classification based on Directive 67/548/EEC.

⁶ Article 9 of Directive 97/23/EC.

The proposed alignment is therefore a technical alignment primarily designed to minimize the impact of the changes in the classification system of the fluids introduced by the CLP Regulation on the classification of the pressure equipment itself.

Consistency with other policies and objectives of the Union

This initiative is in line with the Single Market Act⁷, which stressed the need to restore consumer confidence in the quality of products on the market and the importance of reinforcing market surveillance.

Furthermore it supports the Commission's policy on Better Regulation and simplification of the regulatory environment.

2. CONSULTATION OF THE INTERESTED PARTIES AND IMPACT ASSESSMENT

Consultation of interested parties

a) The alignment of Directive 97/23/EC to the NLF Decision has been discussed with national experts responsible for the implementation of the Directive, the conformity assessment bodies' forum, the administrative cooperation group on market surveillance as well as in bilateral contacts with industry associations.

From June to October 2010 a public consultation was organised that comprised all the sectors involved in this initiative. It consisted of four targeted questionnaires for economic operators, authorities, conformity assessment bodies and users and the Commission services received 300 replies. The results are published at:

http://ec.europa.eu/enterprise/policies/single-market-goods/internal-market-for-products/new-legislative-framework/index_en.htm

In addition to the general consultation a specific SME consultation was carried out. 603 SMEs were consulted through the Enterprise Europe Network in May/June 2010. The results are available at http://ec.europa.eu/enterprise/policies/single-market-goods/files/new-legislative-framework/smes_statistics_en.pdf

The consultation process revealed widespread support for the initiative. There is unanimity on the need to improve market surveillance and the system for assessing and monitoring conformity assessment bodies. Authorities fully support the exercise because it will strengthen the existing system and improve cooperation at EU level. Industry expects a more level playing field resulting from more effective actions against products that do not comply with the legislation, as well as a simplification effect from the alignment of legislation. Certain concerns were expressed on some obligations which are, however, indispensable for increasing the efficiency of market surveillance. These measures will not entail significant costs for industry and the benefits resulting from improved market surveillance should by far outweigh the costs.

⁷ Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions, COM(2011) 206 final.

b) The alignment of Directive 97/23/EC to the CLP Regulation has been discussed with national experts responsible for the implementation of the Directive, the conformity assessment bodies' forum, the administrative cooperation group as well as in bilateral contacts with industry associations.

An impact assessment study on the alignment of Directive 97/23/EC to the CLP Regulation was conducted in 2012.

In the context of this study, a survey was organised amongst key stakeholders. The Commission organised a workshop on 7 November 2012 in order to collect further information and to allow direct interaction with stakeholders. The workshop was attended by representatives of national authorities, user and manufacturer associations, conformity assessment bodies, standardisers and experts in the field of the CLP Regulation.

Collection and use of expertise - Impact assessment

a) Impact assessment concerning the alignment to the NLF Decision

In addition to the general impact assessment for the New Legislative Framework, an impact assessment was conducted for the NLF implementation package adopted in November 2011. That impact assessment covered also the alignment of Directive 97/23/EC to the NLF Decision and was largely built on the general impact assessment carried out for the New Legislative Framework. In addition to the expertise collected and analysed in that context, further consultation of the sector-specific experts and interest groups, as well as horizontal experts active in the area of technical harmonisation, conformity assessment, accreditation and market surveillance, has taken place.

Based on the information collected, the Commission carried out an impact assessment which examined and compared three options.

Option 1 - No changes to the current situation

This option proposes no changes to the current directive and relies exclusively on certain improvements that can be expected from the NLF Regulation.

Option 2 – Alignment to the NLF Decision by non-legislative measures

Option 2 considers the possibility of encouraging a voluntary alignment to the provisions set out in the NLF Decision by, e.g., presenting them as best practices in guidance documents.

Option 3 – Alignment to the NLF Decision by legislative measures

This option consists in integrating the provisions of the NLF Decision into Directive 97/23/EC.

Option 3 was found to be the preferred option because:

- it will improve the competitiveness of companies and conformity assessment bodies taking their obligations seriously;

- it will improve the functioning of the internal market by ensuring equal treatment of all economic operators, notably importers and distributors, as well as conformity assessment bodies;
- it does not entail significant costs for economic operators and conformity assessment bodies; for those who are already acting responsibly, no extra costs or only negligible costs are expected;
- it is considered more effective than option 2: due to the lack of enforceability of option 2 it is questionable that the positive impacts would materialise under that option;
- options 1 and 2 do not provide answers to the problem of inconsistencies in the regulatory framework and therefore have no positive impact on the simplification of the regulatory environment.

As outlined above in option 3, the alignment of Directive 97/23/EC to the NLF Decision will lead to a better implementation of the Directive.

The proposal includes:

- Measures to address the problem of non-compliance by clarifying the obligations of economic operators and requiring enhanced traceability requirements.
- Measures intended to ensure the quality of work done by conformity assessment bodies by reinforcing the notification requirements, revised notification process, specifying requirements for notifying authorities and more stringent information obligations.
- Measures intended to ensure greater consistency amongst Directives by aligning commonly used definitions and terminology and aligning the conformity assessment procedures.

The impact of these measures will lead to strengthening the competitiveness of European enterprises as a result of guaranteeing a level playing field for the economic operators.

b) Impact assessment concerning the alignment to the CLP Regulation

The alignment of Directive 97/23/EC to the CLP Regulation is a direct consequence of implementing the CLP Regulation in the Union.

In particular, the classification of hazardous substances and mixtures is regulated at European level by the CLP Regulation which transposes the international Global Harmonised System (GHS) in the EU.

Therefore, the objective of the alignment of Directive 97/23/EC to the CLP Regulation is to ensure legal coherence. Such an alignment requires only the modification of Article 9(2) of Directive 97/23/EC.

A non-alignment to the CLP Regulation would lead to legal uncertainty as from 1 June 2015, when Directive 67/548/EEC will be repealed, because, as from this date, there would be no legal basis for the classification of pressure equipment based on the fluid it contains.

The evaluation study of Directive 97/23/EC completed in November 2012, concluded that there is no urgent need for a full revision of Directive 97/23/EC. Better implementation of the Directive can be achieved by introducing the NLF provisions and by complementary measures such as improving the market surveillance. Additional studies should be conducted before preparing a full revision of the Directive, analysing e.g. issues related to the scope, technical provisions related to the essential safety requirements, etc... It also confirmed that the current classification mechanism of the pressure equipment provided for by the Directive and based also on the classification of the fluid is satisfactory.

The proposed alignment options are the result of a technical mapping of the current hazard classes of dangerous substances and preparations provided for by Directive 97/23/EC and based on Directive 67/548/EEC to the hazard classes for the classification of substances and mixtures classified as hazardous in accordance with the CLP Regulation. This technical mapping results to minimal changes to the existing classification system of pressure equipment provided for by Directive 97/23/EC.

Similar to the current provisions of Directive 97/23/EC, the proposal should therefore address the physical and health hazards due to the fluids contained in the pressure equipment, as far as relevant for the classification of pressure equipment in view of its conformity assessment.

For most pressure equipment there will be no change of the classification of the equipment due to the alignment to the CLP Regulation.

The best possible mapping between Directive 67/548/EEC and the CLP Regulation should be envisaged reducing the impact of this change to the minimum. The technical detail of the alignment and the options chosen on how to modify Article 9(2) of Directive 97/23/EC could lead to increasing or reducing the number of substances or mixtures included in Group 1 of Directive 97/23/EC (the group which imposes more demanding requirements with regard to the conformity assessment procedures).

The impact of the various options has been analysed in an impact assessment study on the alignment of Directive 97/23/EC to the CLP Regulation, finalised in February 2013.

It results from the analysis that whilst there will be changes in the terminology used to identify the hazards, only a small number of fluids will be classified in a different group under Directive 97/23/EC possibly leading to a different classification of the pressure equipment itself.

A possible change in the classification of the fluids under Directive 97/23/EC does not always necessarily result in a different classification of the pressure equipment itself since such classification of the equipment depends not only on the nature of the fluid but also on the total energetic content (based on the pressure and the volume of the equipment).

In particular, the transition from Directive 67/548/EEC to the CLP Regulation for physical hazards is reasonably smooth as there is a good matching between that Directive and the new classification under the CLP Regulation. Only for a few substances the classification will change because the CLP Regulation introduces new cut-off values for the flammability criteria.

The transition from Directive 67/548/EEC to the CLP Regulation for the health hazards is more complex as the boundaries of some categories do not always align with those of Directive 67/548/EEC, as the CLP Regulation introduces also new hazard classes and categories.

In particular, the hazard classes and categories related to acute toxicity have been analysed more in detail with regard to their potential safety and economic impact.

With regard to the hazard classes for acute toxicity, the findings can be summarized as follows:

- the inclusion of the fluids that are classified under the hazard classes acute oral toxicity category 1 and 2 in Group 1 under Directive 97/23/EC will lead to a decrease in the number of fluids (in the meaning of substances or preparations) in Group 1. This option is supported by the fact that the oral take-up of substances or mixtures due to failure of pressure equipment cannot be excluded but the risk is very limited. This option would therefore not cause an unacceptable safety risk. However, the inclusion of acute oral toxicity category 3 would lead to a substantial increase in the number of fluids in Group 1, possibly resulting in a higher category of the equipment which may lead to an increase of the costs of the conformity assessment, without a substantial gain in the level of safety.

- the inclusion of the fluids that are classified under the hazard classes acute dermal toxicity category 1 and 2 will lead to a small decrease in the number of fluids (in the meaning of substances or preparations) in Group 1 under Directive 97/23/EC. This option is supported by the fact that dermal contact with substances or mixtures due to failure of pressure equipment cannot be excluded but the risk is rather limited and would not cause an unacceptable safety risk. However, the inclusion of acute dermal toxicity category 3 would lead to a relatively small increase in the number of fluids in Group 1, without a substantial gain in the level of safety.

- the inclusion of the fluids that are classified under the hazard classes acute toxicity inhalation category 3 in addition to category 1 and 2 will lead to an increase of fluids (in the meaning of substances or preparations) in Group 1 under Directive 97/23/EC which is justified given the risk that might exist due to small leakages of fluids in the pressure equipment.

In summary, for most of the fluids used in pressure equipment, there will be no change in the classification of the equipment due to the alignment to the CLP Regulation. For a limited number of fluids, used in a limited number of applications, the alignment to the CLP Regulation may lead to a different classification of the equipment and may influence the cost for the conformity assessment process.

The impact assessment study concluded that the impact of the proposed alignment would be limited and in particular that the overall economic impact will be low considering that the proposed alignment options are aiming at the best possible mapping between the current classification (based on Directive 67/548/EEC) and the future one (based on the CLP Regulation).

Based on the number of substances that would be subject to a different classification and the proportion of manufacturers that would be affected, the impact assessment study estimates the overall costs of aligning Directive 97/23/EC to the CLP Regulation to be of the order of 8,5

million euros per year. The cost is due to the changes in the alignment for the health hazard classes.

However, looking at the current compliance costs, and according to the impact assessment study, the total average cost of the conformity assessment for the pressure equipment covered by Directive 97/23/EC is estimated at 236,3 million euros per year.

Therefore, the incremental cost due to the alignment of Directive 97/23/EC to the CLP Regulation is low compared to the total cost for conformity assessment. However, the implementation of the CLP Regulation in the Union is mandatory and the cost cannot be avoided.

The impact assessment study is available at:
http://ec.europa.eu/enterprise/sectors/pressure-and-gas/documents/ped/index_en.htm

On the basis of the above, the Commission concluded that:

- a) There is no alternative course of action because all downstream legislation which is using classification of chemical substances has to be aligned to the CLP Regulation, which is the European Union initiative transposing the international Global Harmonised System (GHS) in the EU. The current legal basis for the classification of substances and preparations, referred to in Article 9(2.1) of Directive 97/23/EC, namely Directive 67/548/EEC, will be repealed on 1 June 2015. By that time, Directive 97/23/EC should be modified and refer to the CLP Regulation for the purpose of the classification of pressure equipment within its scope. The proposed alignment is therefore a technical alignment which is primarily designed to minimize the impact of the changes in the classification system of the pressure equipment itself and to guarantee legal certainty as from 1 June 2015.
- b) The impact assessment study did not identify significant economic or health related impacts.

3. MAIN ELEMENTS OF THE PROPOSAL

3.1. Horizontal definitions

The proposal introduces harmonised definitions of terms which are commonly used throughout Union harmonisation legislation and should therefore be given a consistent meaning throughout that legislation.

3.2. Obligations of economic operators and traceability requirements

The proposal clarifies the obligations of manufacturers and authorised representatives and introduces obligations for importers and distributors. Importers must verify that the manufacturer has carried out the applicable conformity assessment procedure and has drawn up a technical documentation. They must also make sure with the manufacturer that this technical documentation can be made available to authorities upon request. Furthermore importers must verify that pressure equipment is correctly marked and accompanied by the instructions and safety information. They must keep a copy of the Declaration of conformity and indicate their name and address on the product, or where this is not possible on the packaging or the accompanying documentation. Distributors must verify that pressure

equipment bears the CE marking, the name of the manufacturer and of the importer, if relevant, and that it is accompanied by the required documentation and instructions.

Importers and distributors must cooperate with market surveillance authorities and take appropriate actions when they have supplied non-compliant pressure equipment.

Enhanced traceability obligations are introduced for all economic operators. Pressure equipment has to bear the manufacturer's name and address and a number allowing to identify and link the pressure equipment to its technical documentation. When pressure equipment is imported the importer's name and address must also be on the pressure equipment. Furthermore every economic operator must be able to identify towards authorities the economic operator who has supplied him with pressure equipment or to whom he has supplied pressure equipment.

3.3. Harmonised standards

Compliance with harmonised standards provides for a presumption of conformity with the essential requirements. Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European Standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council⁸ sets out a horizontal legal framework for European standardisation. The Regulation contains inter alia provisions on standardisation requests from the Commission to the European Standardisation Organisation, on the procedure for objections to harmonised standards and on stakeholder participation in the standardisation process. Consequently, it repealed Article 6 of Directive 97/23/EC covering the same aspects. The provision conferring presumption of conformity to harmonised standards has been modified to clarify the extent of the presumption of conformity when standards only partially cover the essential requirements.

3.4. Conformity assessment and CE marking

Directive 97/23/EC has selected the appropriate conformity assessment procedures which manufacturers have to apply in order to demonstrate that their pressure equipment complies with the essential safety requirements. The proposal aligns these procedures to their updated versions set out in the NLF Decision.

General principles of the CE marking are set out in Article 30 of Regulation (EC) No 765/2008, while the detailed provisions on the affixing of the CE marking to pressure equipment have been inserted in this proposal.

3.5. Conformity assessment bodies

The proposal reinforces the notification criteria for conformity assessment bodies, namely notified bodies but also recognised third-party organisations and user inspectorates. It clarifies that subsidiaries or subcontractors must also comply with the notification requirements. Specific requirements for notifying authorities are introduced and the procedure for notification of notified bodies and user inspectorates and for designation of recognised third-

⁸ OJ L 316, 14.11.2012, p.12.

party organisations is revised. The competence of conformity assessment bodies must be demonstrated by an accreditation certificate. Where accreditation has not been used to evaluate the competence of a conformity assessment body, the notification must comprise the documentation demonstrating how the competence of that body has been evaluated. Member States will have the possibility to object to a notification.

3.6. Market surveillance and the safeguard clause procedure

On 13 February 2013, the Commission adopted a proposal for a Regulation on market surveillance of products, which intends to set out a single legal instrument on the market surveillance activities in the field of non-food goods, consumer or non-consumer products and products covered or not by Union harmonisation legislation. The proposal merges the rules on market surveillance of Directive 2001/95/EC on general product safety⁹, Regulation (EC) No 765/2008 and sector- specific harmonisation legislation in order to increase the effectiveness of market surveillance activities within the Union. The proposed Regulation covers also the reference provisions on market surveillance and safeguard clauses contained in the NLF Decision. Therefore, provisions in existing Union harmonisation legislation that relate to market surveillance and safeguard clauses should be removed from that harmonisation legislation.

The overarching objective of the proposed Regulation is to simplify the Union market surveillance framework fundamentally so that it works better for its main users: market surveillance authorities and economic operators. This will result in a better implementation of the market surveillance rules across Member States, providing better protection for consumers and other users, reduced administrative burdens and enhanced information and work-sharing between market surveillance authorities.

In this framework, the proposed Regulation will lead to a better implementation of Directive 97/23/EC, which covers consumer and non-consumer products, and to an improved competitiveness framework in the internal market.

On this basis, the proposal does not include provisions on market surveillance and safeguard clause procedures, but in order to ensure legal clarity, it makes a reference to the proposed Regulation on market surveillance of products.

3.7. Classification of pressure equipment

The proposal modifies Article 9(2) of Directive 97/23/EC so as to align, for purposes related to the conformity assessment of the pressure equipment, the current classification of fluids contained in the equipment and which is based on the classification of dangerous substances and preparations provided for by Directive 67/548/EEC, to the new classification of hazardous substances and mixtures provided for by the CLP Regulation.

3.8. Comitology and delegated acts

The provisions on the operation of the Committee on Pressure Equipment have been adapted to the new rules on delegated acts laid down in Article 290 of the Treaty on the Functioning of the EU and to the new provisions on implementing acts laid down in Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the

⁹ OJ L11, 15.1.2002, p.4.

rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers¹⁰.

4. LEGAL ELEMENTS OF THE PROPOSAL

Legal basis

The proposal is based on Article 114 of the Treaty on the Functioning of the European Union.

Subsidiarity principle

The internal market is a competence that is shared between the Union and the Member States. The subsidiarity principle arises in particular with regard to the newly added provisions aiming at the improvement of effective enforcement of Directive 97/23/EC, namely, the importer and distributor obligations, the traceability provisions, the provisions on the assessment and notification of conformity assessment bodies, and the enhanced cooperation obligations in the context of the revised market surveillance and safeguard procedures.

Experience with the enforcement of the legislation has shown that measures taken at national level have led to divergent approaches and to a different treatment of economic operators inside the EU, which undermines the objective of this directive. If actions are taken at national level to address the problems, this risks creating obstacles to the free movement of goods. Furthermore action at national level is limited to the territorial competence of a Member State. In view of the increasing internationalisation of trade, the number of cross-border cases is constantly rising. Coordinated action at EU level can much better achieve the objectives set, and will in particular render market surveillance more effective. Hence it is more appropriate to take action at EU level.

As regards the problem of inconsistencies throughout the directives, this is a problem which can only be solved by the EU legislator.

In accordance with the principle of proportionality, the modifications to be proposed will not go beyond what is necessary to achieve the objectives set.

Proportionality

In accordance with the principle of proportionality, the proposed modifications do not go beyond what is necessary to achieve the objectives set.

The new or modified obligations do not impose unnecessary burdens and costs on industry - especially on small and medium sized enterprises - or administrations. Where modifications have been identified to have negative impacts, the analysis of the impacts of the option serves to provide the most proportionate response to the problems identified. A number of modifications concern the improvement of clarity of the existing Directive without introducing new requirements that entail added cost.

Legislative technique used

¹⁰ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and the general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

The alignment to the NLF Decision and to the CLP Regulation requires a number of substantive amendments to the provisions of Directive 97/23/EC. To ensure the readability of the amended text the technique of recasting has been chosen in line with the Inter-institutional Agreement of 28 November 2001 on a more structured use of the recasting technique for legal acts¹¹.

The changes made to the provisions of Directive 97/23/EC concern: the definitions, the obligations of economic operators, the presumption of conformity provided by harmonised standards, the declaration of conformity, CE marking, conformity assessment bodies, the safeguard clause procedure, the conformity assessment procedures and the classification of the fluids.

The proposal does not change the scope of Directive 97/23/EC and the essential safety requirements.

5. BUDGETARY IMPLICATION

This proposal does not have any implications for the EU budget.

6. ADDITIONAL INFORMATION

Repeal of existing legislation

The adoption of the proposal will lead to repeal of Directive 97/23/EC as from 1 June 2015.

In particular, in order to ensure the simultaneous and coherent implementation of the alignment of Directive 97/23/EC to Decision 768/2008/EC and to Regulation (EC) No 1272/2008, the proposal provides that the new Directive will apply as from 1 June 2015.

European Economic Area

The proposal concerns the EEA and should therefore be extended to the European Economic Area.

¹¹ OJ C 77, 28.3.2002, p. 1.

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

**on the ~~approximation~~ ☒ harmonisation ☒ of the laws of the Member States
concerning ☒ relating to making available on the market of ☒ pressure equipment**

(Recast)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty ~~establishing the European Community~~ ☒ on Functioning of the European Union ☒ and in particular Article ~~100a~~ ☒ 114 ☒ thereof,

Having regard to the proposals from the European Commission,

After transmission of the draft legislative act to the national Parliaments,

Having regard to the Opinion of the European Economic and Social Committee¹²,

Acting in accordance with the ordinary legislative procedure,

Whereas:

↓ new

- (1) Directive 97/23/EC of the European Parliament and of the Council of 29 May 1997 on the approximation of the laws of the Member States concerning pressure equipment¹³ has been substantially amended several times. Since further amendments are to be made, it should be recast in the interests of clarity.
- (2) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93¹⁴ lays down rules on the accreditation of conformity assessment bodies [provides a framework for the market surveillance of products and for controls on products from third countries,] and lays down the general principles of the CE marking.

¹² OJ C [...], [...], p. [...].

¹³ OJ L 181, 9.7.1997, p. 1.

¹⁴ OJ L 218, 13.8.2008, p. 30.

- (3) Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products and repealing Council Decision 93/465/EEC¹⁵ lays down a common framework of general principles and reference provisions intended to apply across the legislation harmonising the conditions for the marketing of products in order to provide a coherent basis for revision or recasts of that legislation. Directive 97/23/EC should therefore be adapted to that Decision.

↓ 97/23/EC recital 1 (adapted)

~~Whereas the internal market is an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured;~~

↓ 97/23/EC recital 2

~~Whereas there are differences in the content and scope of the laws, regulations and administrative provisions in force in the Member States with regard to the safety and protection of health of persons and, where appropriate, domestic animals or property, where pressure equipment not covered by present Community legislation is concerned; whereas the certification and inspection procedures for such equipment differ from one Member State to another; whereas such disparities may well constitute barriers to trade within the Community;~~

↓ 97/23/EC recital 3

~~Whereas the harmonization of national legislation is the only means of removing these barriers to free trade; whereas this objective cannot be achieved satisfactorily by the individual Member States; whereas this Directive only lays down indispensable requirements for the free circulation of the equipment to which it is applicable;~~

↓ 97/23/EC recital 4 (adapted)

- (4) ~~Whereas equipment subject to a pressure of not more than 0,5 bar does not pose a significant hazard due to pressure; whereas there should not therefore be any obstacle to its free movement within the Community;~~ This Directive applies ☒ should apply ☒ to equipment subject to a maximum allowable pressure PS exceeding ☒ greater than ☒ 0,5 bar. ☒ Equipment subject to a pressure of not more than 0,5 bar does not pose a significant risk due to pressure. Therefore, there should not be any obstacle to its free movement within the Union. ☒

↓ 97/23/EC recital 5 (adapted)

- (5) This Directive ~~relates also~~ ☒ should also apply ☒ to assemblies composed of several pieces of pressure equipment assembled to constitute an integrated and functional whole. ~~These~~ ☒ Those ☒ assemblies may range from simple assemblies such as pressure cookers to complex assemblies such as water tube boilers. If the manufacturer

¹⁵ OJ L 218, 13.8.2008, p. 82.

of an assembly intends ~~it to be placed~~ ☒ place it ☒ on the market and put ☒ it ☒ into service as an assembly - and not in the form of its constituent non-assembled elements - that assembly ~~must conform to~~ ☒ should comply with ☒ this Directive. ~~On the other hand~~ ☒ However ☒, this Directive ~~does not cover~~ ☒ should not apply to ☒ the assembly of pressure equipment on the site and under the responsibility of the user, as in the case of industrial installations.

↓ 97/23/EC recital 6 (adapted)

- (6) This Directive ~~harmonises~~ ☒ should harmonise ☒ national provisions on ~~hazards~~ ☒ risks ☒ due to pressure. The other ~~hazards~~ ☒ risks ☒ which this equipment may present ~~accordingly~~ may fall within the scope of other Directives dealing with ~~such hazards~~ ☒ those risks ☒.
- (7) However, ☒ some ☒ pressure equipment ~~may be included among products~~ ☒ is ☒ covered by other Directives based on Article ~~100a~~ ☒ 114 ☒ of the Treaty. The provisions laid down in some of those Directives deal ☒ also ☒ with the ~~hazard~~ ☒ risk ☒ due to pressure. Those ~~provisions~~ ☒ Directives ☒ are considered adequate to provide appropriate protection where the ~~hazard~~ ☒ risk ☒ due to pressure associated with such equipment remains small. Therefore, ~~there are grounds for excluding~~ such equipment ☒ should be excluded ☒ from the scope of this Directive.

↓ 97/23/EC recital 7 (adapted)

⇒ new

- (8) For ☒ some ☒ pressure equipment covered by international ~~Conventions~~, ☒ agreements for its international transport, national ☒ transport and pressure ~~hazards~~ ☒ risks ☒ are ~~due to be dealt with as soon as possible by forthcoming~~ ☒ Union ☒ Directives based on such ~~Conventions~~ ☒ agreements ☒ or by supplements to existing Directives ☒ ⇒ by extending the application of those agreements to national transport, in order to ensure the free movement of such dangerous goods whilst enhancing transport safety ⇐. Such equipment ⇐ which is covered by Directive 2008/68/EC of the European Parliament and of the Council of 29 September 2008 on the inland transport of dangerous goods¹⁶ and by Directive 2010/35/EU of the European Parliament and of the Council of 16 June 2010 on transportable pressure equipment and repealing Council Directives 76/767/EEC, 84/525/EEC, 84/526/EEC, 84/527/EEC and 1999/36/EC¹⁷ ⇐ ~~is accordingly~~ ☒ should be ☒ excluded from the scope of this Directive.

↓ 97/23/EC recital 8 (adapted)

- (9) Certain types of pressure equipment, although subject to a maximum allowable pressure PS ~~higher~~ ☒ greater ☒ than 0,5 bar, do not present any significant ~~hazard~~ ☒ risk ☒ due to pressure, and therefore the ~~freedom of~~ ☒ free ☒ movement of such equipment in the ~~Community~~ ☒ Union ☒ should not be hindered if it has been legally manufactured or placed on the market in a Member Stat. It is not necessary in

¹⁶ OJ L 260, 30.9.2008, p.13.

¹⁷ OJ L 165, 30.6.2010, p.1.

order to ensure free movement of such equipment to include it in the scope of this Directive. Consequently it ~~is~~ ☒ should be ☒ expressly excluded from its scope.

↓ 97/23/EC recital 9 (adapted)

- (10) Other pressure equipment subject to a maximum allowable pressure ~~higher~~ ☒ greater ☒ than 0,5 bar and presenting a significant ~~hazard~~ ☒ risk ☒ due to pressure, but in respect of which free movement and an appropriate level of safety are guaranteed, ~~is~~ ☒ should be ☒ excluded from the scope of this Directive. Such exclusions should, however, be regularly reviewed in order to ascertain whether it is necessary to take action at Union level.

↓ 97/23/EC recital 10

~~Whereas regulations to remove technical barriers to trade must follow the new approach provided for in the Council Resolution of 7 May 1985 on a new approach to technical harmonization and standards¹⁸, which requires a definition of the essential requirements regarding safety and other requirements of society without reducing existing, justified levels of protection within the Member States; whereas that Resolution provides that a very large number of products be covered by a single Directive in order to avoid frequent amendments and the proliferation of Directives;~~

↓ 97/23/EC recital 11

~~Whereas the existing Community Directives on the approximation of the laws of the Member States relating to pressure equipment have made positive steps towards removing barriers to trade in this area; whereas those Directives cover that sector only to a minor extent; whereas Council Directive 87/404/EEC of 25 June 1987 on the harmonization of the laws of the Member States relating to simple pressure vessels¹⁹ is the first case of application of the new approach to the sector of pressure equipment; whereas the present Directive will not apply to the area covered by Directive 87/404/EEC; whereas, no later than three years after the present Directive enters into force, a review will be carried out of the application of Directive 87/404/EEC in order to ascertain the need for the integration thereof into the present Directive;~~

↓ 97/23/EC recital 12

~~Whereas the framework Directive, Council Directive 76/767/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to common provisions for pressure vessels and methods for inspecting them²⁰ is optional; whereas it provides for a procedure for the bilateral recognition of testing and certification of pressure equipment which did not operate satisfactorily and which therefore must be replaced by effective Community measures;~~

¹⁸ OJ No C 136, 4.6.1985, p. 1.

¹⁹ OJ No L 220, 8.8.1987, p. 48. Directive as last amended by Directive 93/68/EEC (OJ No L 220, 30. 8. 1993, p. 1).

²⁰ OJ No L 262, 27.9.1976, p. 153. Directive as last amended by the 1994 Act of Accession.

↓ 97/23/EC recital 13 (adapted)

- (11) The scope of this Directive ~~must~~ ☒ should ☒ be based on a general definition of the term «pressure equipment» so as to allow for the technical development of products.
-

↓ 97/23/EC recital 14 (adapted)

- (12) Compliance with the essential safety requirements is necessary in order to ensure the safety of pressure equipment. Those requirements ~~have been~~ ☒ should be ☒ subdivided into general and specific requirements ~~which must~~ ☒ that need to ☒ be met by pressure equipment. In particular the specific requirements ~~are intended to~~ ☒ should ☒ take account of particular types of pressure equipment. Certain types of pressure equipment in categories III and IV ~~must~~ ☒ should ☒ be subject to a final assessment comprising final inspection and proof tests.
-

↓ 97/23/EC recital 15 (adapted)

- (13) Member States should be in a position to allow the showing at trade fairs of pressure equipment which is not yet in conformity with the requirements of this Directive. During demonstrations, appropriate safety measures ~~must~~ ☒ should ☒ be taken in accordance with the general safety rules of the Member State concerned to ensure the safety of persons.
-

↓ new

- (14) Directive 97/23/EC provides for a classification of pressure equipment in categories, according to the ascending level of risk due to pressure. This includes the classification of the fluid contained in the pressure equipment as dangerous or not, according to Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances²¹. On 1 June 2015 Directive 67/548/EEC is to be repealed and replaced by Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures²², which implements in the Union the Globally Harmonised System of Classification and Labelling of Chemicals that has been adopted at international level, within the United Nations (UN) structure. Regulation (EC) No 1272/2008 introduces new hazard classes and categories only partially corresponding to those provided for by Directive 67/548/EEC. Directive 97/23/EC should therefore be aligned to Regulation (EC) No 1272/2008 while maintaining the existing levels of protection of that Directive.

- (15) Economic operators should be responsible for the compliance of pressure equipment with the requirements of this Directive, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of public interests, such as health and safety and the protection of users, and to guarantee fair competition on the Union market.

²¹ OJ 196, 16.8.1967, p. 1.

²² OJ L 353, 31.12.2008, p. 1.

- (16) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they only make available on the market pressure equipment which is in conformity with this Directive. It is necessary to provide for a clear and proportionate distribution of obligations which correspond to the role of each economic operator in the supply and distribution chain.
- (17) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the complete conformity assessment procedure. Conformity assessment should therefore remain solely the obligation of the manufacturer.
- (18) In order to facilitate the communication between economic operators, national market surveillance authorities and consumers, Member States should encourage economic operators to indicate a website address in addition to the postal address.
- (19) It is necessary to ensure that pressure equipment from third countries entering the Union market complies with the requirements of this Directive, and in particular that appropriate conformity assessment procedures have been carried out by manufacturers with regard to that pressure equipment. Provision should therefore be made for importers to make sure that the pressure equipment they place on the market complies with the requirements of this Directive and that they do not place on the market pressure equipment which does not comply with such requirements or presents a risk. Provision should also be made for importers to make sure that the conformity assessment procedures have been carried out and that marking of pressure equipment and documentation drawn up by manufacturers are available for inspection by the national authorities.
- (20) The distributor makes pressure equipment available on the market after it has been placed on the market by the manufacturer or the importer and should act with due care to ensure that its handling of the pressure equipment does not adversely affect the compliance of the equipment with the requirements of this Directive.
- (21) When placing pressure equipment on the market, every importer should indicate on the pressure equipment his name and the postal address at which he can be contacted. Exceptions should be provided for in cases where the size or nature of the pressure equipment does not allow it. This includes cases where the importer would have to open the packaging to put his name and address on the equipment.
- (22) Any economic operator that either places pressure equipment on the market under its own name or trademark or modifies pressure equipment in such a way that compliance with the requirements of this Directive may be affected should be considered to be the manufacturer and should assume the obligations of the manufacturer.
- (23) Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by the competent national authorities, and should be prepared to participate actively, providing those authorities with all necessary information relating to the pressure equipment concerned.
- (24) Ensuring traceability of pressure equipment throughout the whole supply chain helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates market surveillance authorities' task of tracing economic operators who made non-compliant pressure equipment available on the market.

- (25) When keeping the information required under this Directive for the identification of economic operators, economic operators should not be required to update such information in respect of other economic operators who have either supplied them with a pressure equipment or to whom they have supplied a pressure equipment.
- (26) This Directive should be limited to the expression of the essential safety requirements. In order to facilitate conformity assessment with those requirements it is necessary to provide for presumption of conformity for pressure equipment which is in conformity with harmonised standards that are adopted in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European Standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council²³ for the purpose of expressing detailed technical specifications of those requirements, especially with regard to the design, manufacture and testing of pressure equipment.
- (27) Regulation (EU) No 1025/2012 provides for a procedure for objections to harmonised standards where those standards do not entirely satisfy requirements of this Directive.

↓ 97/23/EC recital 16

~~Whereas in order to ease the task of demonstrating compliance with the essential requirements, standards harmonized at European level are useful, especially with regard to the design, manufacture and testing of pressure equipment, compliance with which enables a product to be presumed to meet the said essential requirements; whereas standards harmonized at European level are drawn up by private bodies and must retain their non-mandatory status; whereas, for this purpose, the European Committee for Standardization (CEN) and the European Committee for Electro-technical Standardization (Cenelec) are recognized as being the bodies that are competent to adopt harmonized standards that follow the general guidelines for cooperation between the Commission and those two bodies signed on 13 November 1984;~~

↓ 97/23/EC recital 17

~~Whereas, for the purposes of this Directive, a harmonized standard is a technical specification (European standard or harmonization document) adopted by one or other of those bodies, or by both, at the request of the Commission pursuant to Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations²⁴ and in accordance with the general guidelines referred to above; whereas, in relation to standardization, it would be advisable for the Commission to be assisted by the Committee set up pursuant to Directive 83/189/EEC; whereas the Committee will, if necessary, consult technical experts;~~

²³ OJ L 316, 14.11.2012, p. 12.

²⁴ OJ No L 109, 26. 4. 1983, p. 8. Directive as last amended by the 1994 Act of Accession.

↓ 97/23/EC recital 18 (adapted)

⇒ new

- (28) Manufacturing of pressure equipment calls for the utilisation of safe materials. In the absence of harmonised standards, ~~it is useful to define~~ the characteristics of the materials intended for repeated use ☒ should be established. Those characteristics should be ☒ ~~This definition is~~ established by European approvals for materials, such approvals being issued by one of the notified bodies specifically designated for that task. The materials conforming to the European approvals ~~shall be presumed to satisfy~~ ☒ should benefit from presumption of conformity with ☒ the essential ⇒ safety ⇐ requirements of this Directive.
-

↓ 97/23/EC recital 19 (adapted)

⇒ new

- (29) In view of the nature of the ~~hazards~~ ☒ risks ☒ involved in the use of pressure equipment ⇒ and in order to enable economic operators to demonstrate and the competent authorities to ensure that pressure equipment made available on the market conforms to the essential safety requirements, ⇐ it is necessary to establish ⇒ provide for conformity assessment ⇐ procedures ~~for assessing compliance with the basic requirements of the Directives~~. These procedures ~~must~~ ☒ should ☒ be devised in the light of the level of danger which is inherent in the pressure equipment. Therefore, for each category of pressure equipment there ~~must~~ ☒ should ☒ be an adequate procedure or a choice between different procedures of equivalent stringency. ~~whereas the procedures adopted are as required by Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonization Directives²⁵;~~ ⇐ Decision No 768/2008/EC establishes modules for conformity assessment procedures, which include procedures from the least to the most stringent, in proportion to the level of risk involved and the level of safety required. In order to ensure inter-sectoral coherence and to avoid ad-hoc variants, conformity assessment procedures should be chosen from among those modules. ⇐ The details added to ~~these~~ ☒ those ☒ procedures are justified by the nature of the verification required for pressure equipment.
-

↓ 97/23/EC recital 20 (adapted)

- (30) Member States should be in a position to authorize user inspectorates to carry out certain tasks for conformity assessment in the framework of this Directive. For that purpose this Directive ☒ should ☒ sets out criteria for the authorization of user inspectorates by Member States.

²⁵ OJ No L 220, 30. 8. 1993, p. 23.

↓ 97/23/EC recital 21 (adapted)

- (31) ~~Under the conditions laid down by this Directive,~~ certain procedures for conformity assessment ~~may require~~ ☒ it should be possible for ☒ each item to be inspected and tested by a notified body or a user inspectorate as part of the final assessment of the pressure equipment. In other cases provision should be made to ensure that the final assessment may be monitored by a notified body by means of unexpected visits.
-

↓ new

- (32) Manufacturers should draw up an EU declaration of conformity to provide information required under this Directive on the conformity of the pressure equipment with the requirements of this Directive and of other relevant Union harmonisation legislation.
- (33) To ensure effective access to information for market surveillance purposes, the information required to identify all applicable Union acts should be available in a ‘single EU declaration of conformity’.
-

↓ 97/23/EC recital 22 (adapted)

⇒ new

- (34) Pressure equipment ~~will~~ ☒ should ☒, as a general rule, bear the CE marking. ~~affixed either by the manufacturer or by his authorized representative established within the Community; whereas the CE marking means that the pressure equipment complies with the provisions of this Directive and those of other applicable Community directives on CE marking;~~ ⇒ The CE marking, indicating the conformity of pressure equipment, is the visible consequence of a whole process comprising conformity assessment in a broad sense. General principles governing the CE marking and its relationship to other markings are set out in Regulation (EC) No 765/2008. Rules governing the affixing of the CE marking should be laid down in this Directive. ⇐
- (35) For pressure equipment defined in this Directive which presents only a minor pressure ~~hazard~~ ☒ risk ☒ and for which certification procedures are therefore not justified, the CE marking ~~will~~ ☒ should ☒ not be affixed.
-

↓ new

- (36) The conformity assessment procedures set out in this Directive require the intervention of conformity assessment bodies, which are notified by the Member States to the Commission.
- (37) Experience has shown that the criteria set out in Directive 97/23/EC that conformity assessment bodies have to fulfil to be notified to the Commission are not sufficient to ensure a uniformly high level of performance of these bodies throughout the Union. It is, however, essential that all conformity assessment bodies perform their functions to the same level and under conditions of fair competition. That requires the setting of obligatory requirements for conformity assessment bodies wishing to be notified in order to provide conformity assessment services.

- (38) In order to ensure a consistent level of conformity assessment quality, it is also necessary to set requirements for notifying authorities and other bodies involved in the assessment, notification and monitoring of conformity assessment bodies.
- (39) If a conformity assessment body demonstrates conformity with the criteria laid down in harmonised standards, it should be presumed to comply with the corresponding requirements set out in this Directive.
- (40) The system set out in this Directive should be complemented by the accreditation system provided for in Regulation (EC) No 765/2008. Since accreditation is an essential means of verifying the competence of conformity assessment bodies, it should also be used for the purposes of notification.
- (41) Transparent accreditation as provided for in Regulation (EC) No 765/2008, ensuring the necessary level of confidence in conformity certificates, should be considered by the national public authorities throughout the Union as the preferred means of demonstrating the technical competence of conformity assessment bodies. However, national authorities may consider that they possess the appropriate means of carrying out that evaluation themselves. In such cases, in order to ensure the appropriate level of credibility of evaluations carried out by other national authorities, they should provide the Commission and the other Member States with the necessary documentary evidence demonstrating the compliance of the conformity assessment bodies evaluated with the relevant regulatory requirements.
- (42) Conformity assessment bodies frequently subcontract parts of their activities linked to the assessment of conformity or have recourse to a subsidiary. In order to safeguard the level of protection required for the pressure equipment to be placed on the Union market, it is essential that conformity assessment subcontractors and subsidiaries fulfil the same requirements as notified bodies in relation to the performance of conformity assessment tasks. Therefore, it is important that the assessment of the competence and the performance of bodies to be notified and the monitoring of bodies already notified cover also activities carried out by subcontractors and subsidiaries.
- (43) It is necessary to increase the efficiency and transparency of the notification procedure and, in particular, to adapt it to new technologies so as to enable online notification.
- (44) Since conformity assessment bodies may offer their services throughout the Union, it is appropriate to give the other Member States and the Commission the opportunity to raise objections concerning a notified body. It is therefore important to provide for a period during which any doubts or concerns as to the competence of conformity assessment bodies can be clarified before they start operating as notified bodies.
- (45) In the interests of competitiveness, it is crucial that conformity assessment bodies apply the conformity assessment procedures without creating unnecessary burdens for economic operators. For the same reason, and to ensure equal treatment of economic operators, consistency in the technical application of the conformity assessment procedures needs to be ensured. That can best be achieved through appropriate coordination and cooperation between conformity assessment bodies.
- (46) Member States should take all appropriate measures to ensure that pressure equipment may be placed on the market only if, when properly stored and used for their intended purpose, or under conditions of use which can be reasonably foreseen, they do not

endanger the health and safety of persons. Pressure equipment should be considered as non-compliant with the essential safety requirements laid down in this Directive only under conditions of use which can be reasonably foreseen, that is when such use could result from lawful and readily predictable human behaviour.

↓ 97/23/EC recital 23

~~Whereas it is appropriate that the Member States, as provided for by Article 100a of the Treaty, may take provisional measures to limit or prohibit the placing on the market, putting into service and use of pressure equipment in cases where it presents a particular risk to the safety of persons and, where appropriate, domestic animals or property, provided that the measures are subject to a Community control procedure;~~

↴ new

(47) Regulation (EU) No [.../...] [on market surveillance of products] providing for a single Union legal instrument relating to market surveillance of products, applies to pressure equipment.

↓ 97/23/EC recital 24

~~Whereas the addressees of any decision taken under this Directive must be aware of the reasons behind that decision and the means of appeal open to them;~~

↓ 97/23/EC recital 25

~~Whereas it is necessary to lay down a transitional arrangement enabling pressure equipment manufactured in compliance with the national regulations in force on the date of entry into force of this Directive to be marketed and put into service;~~

↓ 97/23/EC recital 26

~~Whereas the requirements laid down in the Annexes should be made as clear as possible so as to allow all users, including small and medium-sized enterprises (SMEs), to comply with them easily;~~

↓ 97/23/EC recital 27

~~Whereas an agreement on a *modus vivendi* between the European Parliament, the Council and the Commission concerning the implementing measures for acts adopted in accordance with the procedure laid down in Article 189b of the Treaty was reached on 20 December 1994²⁶;~~

²⁶ OJ No C 102, 4. 4. 1996, p. 1.

- (48) In order to ensure uniform conditions for the implementation of this Directive, implementing powers should be conferred to the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers²⁷.
- (49) The advisory procedure should be used for the adoption of implementing acts requesting the notifying Member State to take the necessary corrective measures in respect of notified bodies that do not meet or no longer meet the requirements for their notification.
- (50) The examination procedure should be used for the adoption of implementing acts with respect to European approvals for materials presenting shortcomings and whose references were already published in the *Official Journal of the European Union*, given that such decisions could have consequences on the presumption of conformity with the applicable essential requirements.
- (51) In order to take into account the technical developments in pressure equipment technology, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission in respect of amendments to classification of pressure equipment. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level.
- (52) The Commission, when preparing and drawing-up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.
- (53) Directive 97/23/EC provides for a transitional arrangement enabling pressure equipment and assemblies which comply with the national regulations in force on the date of application of Directive 97/23/EC to be put into service. For reasons of legal certainty, it is necessary to include that transitional arrangement also in this Directive.
- (54) It is necessary to provide for transitional arrangements that allow the making available on the market and the putting into service of pressure equipment which complies with Directive 97/23/EC.
- (55) Member States should lay down rules on penalties applicable to infringements of the provisions of national law adopted pursuant to this Directive and ensure that they are implemented. Those penalties must be effective, proportionate and dissuasive.
- (56) Since the objective of this Directive, namely to ensure that pressure equipment on the market fulfils the requirements providing a high level of protection of health and safety of users and protection of domestic animals or property while guaranteeing the functioning of the internal market cannot be sufficiently achieved by the Member States and can therefore, by reason of its scale and effects, be better achieved at Union

²⁷ OJ L 55, 28.2.2011, p. 13.

level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective.

(57) The obligation to transpose this Directive into national law should be confined to those provisions which represent a substantive change as compared with Directive 97/23/EC. The obligation to transpose the provisions which are unchanged arises under Directive 97/23/EC.

(58) This Directive should be without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law and application of Directive 97/23/EC set out in Part B of Annex V,

↓ 97/23/EC (adapted)

HAVE ADOPTED THIS DIRECTIVE:

CHAPTER 1

⊠ GENERAL PROVISIONS ⊠

Article 1

Scope and definitions

1. This Directive ~~applies~~ ⊠ shall apply ⊠ to the design, manufacture and conformity assessment of pressure equipment and assemblies with a maximum allowable pressure PS greater than 0,5 bar.

~~3.2. The following are excluded from the scope of~~ This Directive ⊠ shall not apply to ⊠ :

↓ 97/23/EC (adapted)

~~3.1.(a)~~ pipelines comprising piping or a system of piping designed for the conveyance of any fluid or substance to or from an installation (onshore or offshore) starting from and including the last isolation device located within the confines of the installation, including all the annexed equipment designed specifically for pipelines; ~~the~~ this exclusion ~~does~~ ⊠ shall ⊠ not apply to standard pressure equipment such as may be found in pressure reduction stations or compression stations;

~~3.2.(b)~~ networks for the supply, distribution and discharge of water and associated equipment and headraces such as penstocks, pressure tunnels, pressure shafts for hydroelectric installations and their related specific accessories;

↓ 97/23/EC (adapted)

3.3.(c) equipment ☒ simple pressure vessels ☒ covered by Directive 87/404/EEC 2009/105/EC of the European Parliament and of the Council²⁸ ~~on simple pressure vessels;~~

3.4.(d) equipment ☒ aerosol dispensers ☒ covered by Council Directive 75/324/EEC²⁹ ~~of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers;~~

3.5.(e) equipment intended for the functioning of vehicles defined by the following Directives ~~and their Annexes:~~

↓ 97/23/EC (adapted)

- (i) Directive 70/156/EEC of 6 February 1970 2007/46/EC of the European Parliament and of the Council³⁰ ~~on the approximation of the laws of the Member States relating to the type-approval of motor vehicles and their trailers~~ establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles;
- (ii) Directive 74/150/EEC 2003/37/EC of the European Parliament and of the Council³¹ 4 March 1974 ~~on the approximation of the laws of the Member States relating to the type-approval of wheeled~~ agricultural or forestry tractors, their trailers and interchangeable towed machinery, together with their systems, components and separate technical units;
- (iii) Directive 92/61/EEC 2002/24/EC of the European Parliament and of the Council³² 30 June 1992 relating to the type-approval of two or three-wheel motor vehicles;

3.6.(f) equipment classified as no higher than category I under Article 9 of this Directive and covered by one of the following Directives:

- (i) Directive 89/392/EEC 2006/42/EC of the European Parliament and of the Council³³ 14 June 1989 ~~on the approximation of the laws of the Member States relating to~~ machinery;

²⁸ OJ L 264, 8.10.2009, p. 12.

²⁹ OJ L 147, 9.6.1975, p. 40. ~~Directive as last amended by Commission Directive 94/1/EC (OJ No L 23, 28. 1. 1994, p. 28).~~

³⁰ OJ L 263, 9.10.2007, p. 1. OJ No L 42, 23. 2. 1970, p. 1. ~~Directive as last amended by Commission Directive 95/54/EC (OJ No L 266, 8. 11. 1995, p. 1).~~

³¹ OJ L 171, 9.7.2003, p. 1. OJ No L 84, 28. 3. 1974, p. 10. ~~Directive as last amended by the 1994 Act of Accession.~~

³² OJ L 124, 9.5.2002, p. 1. OJ No L 225, 10. 8. 1992, p. 72. ~~Directive as last amended by the 1994 Act of Accession.~~

³³ OJ L 157, 9.6.2006, p. 24. OJ No L 183, 29. 6. 1989, p. 9. ~~Directive as last amended by Directive 93/68/EEC (OJ No L 220, 30. 8. 1993, p. 1).~~

- (ii) Directive 95/16/EC of ~~29 June 1995~~ the European Parliament and of the Council³⁴ on ~~the approximation of the laws of the Member States relating to~~ lifts;
- (iii) Directive ~~73/23/EEC~~ 2006/95/EC of the European Parliament and of the Council³⁵ ~~19 February 1973 on the harmonisation of the laws of the Member States~~ relating to electrical equipment designed for use within certain voltage limits;
- (iv) Council Directive 93/42/EEC ~~of 14 June 1993~~ concerning medical devices³⁶;
- (v) Directive ~~90/396/EEC~~ 2009/142/EC of the European Parliament and of the Council³⁷ ~~29 June 1990 on the approximation of the laws of the Member States~~ relating to appliances burning gaseous fuels;
- (vi) Directive 94/9/EC of the European Parliament and of the Council³⁸ ~~of 23 March 1994 on the approximation of the laws of the Member States~~ concerning equipment and protective systems intended for use in potentially explosive atmospheres;

~~3.7.(g)~~ equipment covered by Article ~~223~~ ☒ 346 ☒ (1) (b) of the Treaty;

~~3.8.(h)~~ items specifically designed for nuclear use, failure of which may cause an emission of radioactivity;

~~3.9.(i)~~ well-control equipment used in the petroleum, gas or geothermal exploration and extraction industry and in underground storage which is intended to contain and/or control well pressure; ~~¶~~ ☒ this ☒ shall ☒ comprises the wellhead (Christmas tree), the blow out preventers (BOP), the piping manifolds and all their equipment upstream;

~~3.10.(j)~~ equipment comprising casings or machinery where the dimensioning, choice of material and manufacturing rules are based primarily on requirements for sufficient strength, rigidity and stability to meet the static and dynamic operational effects or other operational characteristics and for which pressure is not a significant design factor; ~~¶~~ Such equipment may include:

- (i) engines including turbines and internal combustion engines;
- (ii) steam engines, gas/steam turbines, turbo-generators, compressors, pumps and actuating devices;

~~3.11.(k)~~ blast furnaces including the furnace cooling system, hot-blast recuperators, dust extractors and blast-furnace exhaust-gas scrubbers and direct reducing cupolas, including the

³⁴ OJ L 213, 7.9.1995, p. 1.

³⁵ OJ L 374, 27.12.2006, p. 10. ~~OJ No L 77, 26.3.1973, p. 29. Directive as last amended by Directive 93/68/EEC (OJ No L 220, 30. 8. 1993, p. 1).~~

³⁶ OJ L 169, 12.7.1993, p. 1.

³⁷ OJ L 330, 16.12.2009, p. 10. ~~OJ No L 196, 26.7.1990, p. 15. Directive as last amended by Directive 93/68/EEC (OJ No L 220, 30. 8. 1993, p. 1).~~

³⁸ OJ L 100, 19.4.1994, p. 1.

furnace cooling, gas converters and pans for melting, re-melting, de-gassing and casting of steel and non-ferrous metals;

3.12.(l) enclosures for high-voltage electrical equipment such as switchgear, control gear, transformers, and rotating machines;

3.13.(m) pressurized pipes for the containment of transmission systems, e.g. for electrical power and telephone cables;

3.14.(n) ships, rockets, aircraft and mobile off-shore units, as well as equipment specifically intended for installation on board or the propulsion thereof;

3.15.(o) pressure equipment consisting of a flexible casing, e.g. tyres, air cushions, balls used for play, inflatable craft, and other similar pressure equipment;

3.16.(p) exhaust and inlet silencers;

3.17.(q) bottles or cans for carbonated drinks for final consumption;

3.18.(r) vessels designed for the transport and distribution of drinks having a PS·V of not more than 500 bar·L and a maximum allowable pressure not exceeding 7 bar;

↓ 97/23/EC (adapted)

3.19.(s) equipment covered by ☒ Directive 2008/68/EC and Directive 2010/35/EU and equipment covered by ☒ ADR³⁹, ~~the RID⁴⁰~~, the ☒ International Maritime Dangerous Goods Code ☒ (IMDG)⁴¹ and the ☒ Convention on International Civil Aviation ☒ (ICAO Convention)⁴²;

↓ 97/23/EC

3.20.(t) radiators and pipes in warm water heating systems;

3.21.(u) vessels designed to contain liquids with a gas pressure above the liquid of not more than 0,5 bar.

↓ 97/23/EC (adapted)

Article 2

☒ Definitions ☒

For the purposes of this Directive ☒ the following definitions apply ☒ :

³⁹ ~~ADR = European Agreement concerning the International Carriage of Dangerous Goods by Road.~~

⁴⁰ ~~RID = Regulations concerning the International Carriage of Dangerous Goods by Rail.~~

⁴¹ ~~IMDG = International Maritime Dangerous Goods Code.~~

⁴² ~~ICAO = International Civil Aviation Organization.~~

2.1.1(1) ~~'P~~pressure equipment' means vessels, piping, safety accessories and pressure accessories, ~~including, where applicable, pressure equipment includes~~ elements attached to pressurized parts, such as flanges, nozzles, couplings, supports, lifting lugs, etc.;

↓ 97/23/EC

2.1.1(2) ~~'V~~vessel' means a housing designed and built to contain fluids under pressure including its direct attachments up to the coupling point connecting it to other equipment; ~~A~~ vessel may be composed of more than one chamber;

2.1.2(3) ~~'P~~piping' means piping components intended for the transport of fluids, when connected together for integration into a pressure system; ~~P~~piping includes in particular a pipe or system of pipes, tubing, fittings, expansion joints, hoses, or other pressure-bearing components as appropriate; ~~H~~heat exchangers consisting of pipes for the purpose of cooling or heating air shall be considered as piping;

↓ 97/23/EC (adapted)

2.1.3(4) ~~'S~~safety accessories' means devices designed to protect pressure equipment against the allowable limits being exceeded, ~~Such devices include~~ including ~~devices for direct pressure limitation, such as safety valves, bursting disc safety devices, buckling rods, controlled safety pressure relief systems (CSPRS), and limiting devices, which either activate the means for correction or provide for shutdown or shutdown and lockout, such as pressure switches or temperature switches or fluid level switches and «safety related measurement control and regulation (SRMCR)» devices;~~

↓ 97/23/EC

2.1.4(5) ~~'P~~pressure accessories' means devices with an operational function and having pressure-bearing housings;

2.1.5(6) ~~'A~~assemblies' means several pieces of pressure equipment assembled by a manufacturer to constitute an integrated and functional whole;

2.2(7) ~~'P~~pressure' means pressure relative to atmospheric pressure, i.e. gauge pressure. As a consequence, vacuum is designated by a negative value;

2.3(8) ~~'M~~maximum allowable pressure PS' means the maximum pressure for which the equipment is designed, as specified by the manufacturer;

↓ 97/23/EC (adapted)

~~It is~~ ~~defined at a location specified by the manufacturer~~ ~~him, being either~~ ~~This must be the location of~~ ~~the~~ connection of protective and/or limiting devices, or the top of equipment or, if not appropriate, any point specified.

↓ 97/23/EC

2.4(9) ~~'M~~maximum/minimum allowable temperature TS' means the maximum/minimum temperatures for which the equipment is designed, as specified by the manufacturer;

~~2.5.~~(10) '~~V~~volume (V)' means the internal volume of a chamber, including the volume of nozzles to the first connection or weld and excluding the volume of permanent internal parts;

~~2.6.~~(11) '~~N~~nominal size (DN)' means a numerical designation of size which is common to all components in a piping system other than components indicated by outside diameters or by thread size; ~~I~~it is a convenient round number for reference purposes and is only loosely related to manufacturing dimensions; ~~T~~the nominal size is designated by DN followed by a number;

~~2.7.~~(12) '~~F~~fluids' means gases, liquids and vapours in pure phase as well as mixtures thereof. A fluid may contain a suspension of solids;

~~2.8.~~(13) '~~P~~permanent joints' means joints which cannot be disconnected except by destructive methods;

~~2.9.~~(14) 'European approval for materials' means a technical document defining the characteristics of materials intended for repeated use in the manufacture of pressure equipment which are not covered by any harmonised standard;

↓ new

(15) 'making available on the market' means any supply of pressure equipment for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

(16) 'placing on the market' means the first making available of pressure equipment on the Union market;

(17) 'manufacturer' means any natural or legal person who manufactures pressure equipment or has such equipment designed or manufactured, and markets that product under his name or trademark;

(18) 'authorised representative' means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;

(19) 'importer' means any natural or legal person established within the Union who places pressure equipment from a third country on the Union market;

(20) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes pressure equipment available on the market;

(21) 'economic operators' means the manufacturer, the authorised representative, the importer and the distributor;

(22) 'technical specification' means a document that prescribes technical requirements to be fulfilled by pressure equipment, process or service;

(23) 'harmonised standard' means harmonised standard as defined in Article 2(1)(c) of Regulation (EU) No 1025/2012;

(24) ‘accreditation’ means accreditation as defined in Article 2(10) of Regulation (EC) No 765/2008;

(25) ‘national accreditation body’ means national accreditation body as defined in Article 2(11) of Regulation (EC) No 765/2008;

(26) ‘conformity assessment’ means the process demonstrating whether the requirements of this Directive relating to pressure equipment, process, service, or a system have been fulfilled;

(27) ‘conformity assessment body’ means a body that performs conformity assessment activities including calibration, testing, certification and inspection;

(28) ‘recall’ means any measure aimed at achieving the return of pressure equipment that has already been made available to the user;

(29) ‘withdrawal’ means any measure aimed at preventing pressure equipment in the supply chain from being made available on the market;

(30) ‘CE marking’ means a marking by which the manufacturer indicates that the pressure equipment and/or the assembly is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing;

(31) ‘Union harmonisation legislation’ means any Union legislation harmonising the conditions for the marketing of products.

↓ 97/23/EC (adapted)

⇒ new

Article 23

~~Market surveillance~~ ☒ ~~Making available on the market and putting into service~~ ☒

1. Member States shall take all appropriate measures to ensure that ~~the pressure equipment and the assemblies referred to in Article 1 may be placed~~ ⇒ made available ⇐ on the market and put into service only if, ~~when properly installed and maintained and used for their intended purpose, they do not endanger the health and safety of persons and, where appropriate, domestic animals or property~~ ⇒ they satisfy the requirements of this Directive ⇐.

2. ~~The provisions of~~ This Directive shall not affect Member States' entitlement to lay down, ~~with due regard to the provisions of the Treaty,~~ such requirements as they may deem necessary to ensure that persons and, in particular, workers are protected during use of the pressure equipment ~~or assemblies~~ in question provided that this does not mean modifications to such equipment ~~or assemblies~~ in a way not specified in this Directive.

3. At trade fairs, exhibitions, demonstrations, ~~etc.,~~ ☒ and other similar events, ☒ Member States shall not prevent the showing of pressure equipment ~~or assemblies as defined in Article 1 not in conformity~~ ☒ which do not comply ☒ with ~~the provisions of~~ this Directive, provided that a visible sign clearly indicates their non-conformity and their non-availability

for sale until ~~⊗~~ they are ~~⊗~~ brought into conformity by the manufacturer or by his authorized representative ~~established within the Community~~. During demonstrations, appropriate safety measures shall be taken in accordance with any requirements laid down by the competent authority of the Member State concerned in order to ensure the safety of persons.

Article ~~34~~

Technical requirements

1. The ~~⊗~~ following ~~⊗~~ pressure equipment ~~referred to in 1.1, 1.2, 1.3 and 1.4~~ must satisfy the essential ~~⊗~~ safety ~~⊗~~ requirements set out in Annex I:

↓ 97/23/EC
→₁ Corrigendum 97/23/EC

~~1.1.(a)~~ ~~V~~vessels, except those referred to in ~~1.2~~ point (b) for:

- (~~ai~~) gases, liquefied gases, gases dissolved under pressure, vapours and also those liquids whose vapour pressure at the maximum allowable temperature is greater than 0,5 bar above normal atmospheric pressure, (1013 mbar) within the following limits:
 - for fluids in Group 1 with a volume greater than 1 L and a product of PS and V greater than 25 bar·L, or with a pressure PS greater than 200 bar (Annex II, table 1)~~);~~
 - for fluids in Group 2, with a volume greater than 1 L and a product of PS and V is greater than 50 bar·L, or with a pressure PS greater than 1000 bar, and all portable extinguishers and bottles for breathing apparatus (Annex II, table 2);
- (~~bi~~) liquids having a vapour pressure at the maximum allowable temperature of not more than 0,5 bar above normal atmospheric pressure (1013 mbar) within the following limits:
 - for fluids in Group 1 with a volume greater than 1 L and a product of PS and V greater than 200 bar·L, or with a pressure PS greater than 500 bar (Annex II, table 3)~~);~~
 - for fluids in Group 2 with a pressure PS greater than 10 bar and a product of PS and V greater than 10000 bar·L, or with a pressure PS greater than 1000 bar (Annex II, table 4).

~~1.2.(b)~~ ~~F~~ired or otherwise heated pressure equipment with the risk of overheating intended for generation of steam or super-heated water at temperatures higher than →₁ 110 °C ← having a volume greater than 2 L, and all pressure cookers (Annex II, table 5).

~~1.3.(c)~~ ~~P~~iping intended for:

- (~~ai~~) gases, liquefied gases, gases dissolved under pressure, vapours and those liquids whose vapour pressure at the maximum allowable temperature is greater than 0,5 bar above normal atmospheric pressure (1013 mbar) within the following limits:
- for fluids in Group 1 with a DN greater than 25 (Annex II, table 6);
 - for fluids in Group 2 with a DN greater than 32 and a product of PS and DN greater than 1000 bar (Annex II, table 7);
- (~~bii~~) liquids having a vapour pressure at the maximum allowable temperature of not more than 0,5 bar above normal atmospheric pressure (1013 mbar), within the following limits:
- for fluids in Group 1 with a DN greater than 25 and a product of PS and DN greater than 2000 bar (Annex II, table 8);
 - for fluids in Group 2 with a PS greater than 10 bar, a DN greater than 200 and a product of PS and DN greater than 5000 bar (Annex II, table 9).

↓ 97/23/EC (adapted)

~~1.4.(d)~~ Safety and pressure accessories intended for equipment covered by ~~1.1, 1.2 and 1.3~~ subparagraphs (a), (b), and (c) including where such equipment is incorporated into an assembly.

2. The ~~☒~~ following ~~☒~~ assemblies defined in ~~Article 1, section 2.1.5~~, which include at least one item of pressure equipment covered by ~~section paragraph 1 of this Article and which are listed in 2.1, 2.2 and 2.3 of this Article~~ must satisfy the essential ~~☒~~ safety ~~☒~~ requirements set out in Annex I.

↓ 97/23/EC
 →₁ Corrigendum 97/23/EC
 ⇨ new

~~2.1.(a)~~ Assemblies intended for generating steam or superheated water at a temperature higher than →₁ 110 °C ← comprising at least one item of fired or otherwise heated pressure equipment presenting a risk of overheating.

~~2.2.(b)~~ Assemblies other than those referred to in ~~2.1 point (a)~~, if the manufacturer intends them to be ~~placed~~ ⇨ made available ⇨ on the market and put into service as assemblies.

↓ 97/23/EC (adapted)
 ⇨ new

~~2.3.~~ By way of derogation from the ~~first subparagraph introductory paragraph to this section~~, assemblies intended for generating warm water at temperatures not greater than 110 °C which are manually fed with solid fuels and have a PS·V greater than 50 bar·L must comply with the essential ~~☒~~ safety ~~☒~~ requirements referred to in ~~points~~ 2.10, 2.11, 3.4, 5 (a) and 5 (d) of Annex I.

3. Pressure equipment ~~and/or assemblies~~ below or equal to the limits ☒ set out ☒ in ~~sections 1.1, 1.2~~ points (a), (b) and (c) of paragraph 1 and in paragraph 2 ~~and 1.3 and section 2~~ respectively ~~must~~ ☒ shall ☒ be designed and manufactured in accordance with the sound engineering practice of a Member State in order to ensure safe use. Pressure equipment ~~and/or assemblies~~ must be accompanied by adequate instructions for use ~~and must bear markings to permit identification of the manufacturer or of his authorized representative established within the Community.~~ Such equipment ~~and/or assemblies must~~ ☒ shall ☒ not bear the CE marking referred to in Article ~~15~~18.

Article 45

Free movement

1. ~~1.1.~~ Member States shall not, on grounds of the ~~hazards~~ ☒ risks ☒ due to pressure, prohibit, restrict or impede the ~~placing~~ ☒ making available ☒ on the market or ☒ the ☒ putting into service under the conditions specified by the manufacturer of pressure equipment ~~or assemblies referred to in Article 1~~ which comply with this Directive ~~and bear the CE marking indicating that they have undergone conformity assessment in accordance with Article 10.~~

~~1.2.~~ Member States shall not, on grounds of the ~~hazards~~ ☒ risks ☒ due to pressure, prohibit, restrict or impede the ~~placing~~ ☒ making available ☒ on the market or ☒ the ☒ putting into service of pressure equipment ~~or assemblies~~ which comply with Article ~~34~~34(3).

2. Member States may require, to the extent that it is needed for safe and correct use of pressure equipment ~~and assemblies~~, the information referred to in ~~Annex I sections points~~ 3.3 and 3.4 ~~of Annex I~~ to be provided in the official language(s) of the ~~Community~~ ☒ Union ☒ which may be determined ~~in accordance with the Treaty~~ by the Member State in which the equipment ~~or assembly~~ reaches the final user.

~~14.2.3.~~ When a Member State has designated a user inspectorate in accordance with the ~~criteria~~ ☒ requirements ☒ set out in ~~this~~ Article ☒ 25 ☒ , it may not, on grounds of the ~~hazards~~ ☒ risks ☒ due to pressure, prohibit, restrict or impede the placing on the market or putting into service under the conditions provided for in ~~this~~ Article ~~16~~, of pressure equipment ~~or assemblies~~ the conformity of which has been assessed by a user inspectorate designated by another Member State in accordance with the ~~criteria~~ ☒ requirements ☒ set out in ~~this~~ Article ☒ 25 ☒ .

CHAPTER 2

OBLIGATIONS OF ECONOMIC OPERATORS

Article 6 [Article R2 of Decision No 768/2008/EC]

Obligations of manufacturers

1. When placing their pressure equipment referred to in Article 4(1) and (2) on the market, manufacturers shall ensure that they have been designed and manufactured in accordance with the essential safety requirements set out in Annex I.

When placing their pressure equipment referred to in Article 4(3) on the market, manufacturers shall ensure that they have been designed and manufactured in accordance with the sound engineering practice of a Member State.

2. For pressure equipment referred to in Article 4(1) and (2), manufacturers shall draw up the technical documentation referred to in Annex II and carry out the conformity assessment procedure referred to in Article 14 or have it carried out.

Where compliance of pressure equipment referred to in Article 4(1) and (2), with the applicable requirements has been demonstrated by the procedure referred to in the first subparagraph, manufacturers shall draw up an EU declaration of conformity and affix the CE marking.

3. Manufacturers shall keep the technical documentation and the EU declaration of conformity for 10 years after the pressure equipment has been placed on the market.

4. Manufacturers shall ensure that procedures are in place for series production to remain in conformity. Changes in pressure equipment design or characteristics and changes in the harmonised standards or in other technical specifications by reference to which conformity of pressure equipment is declared shall be adequately taken into account.

When deemed appropriate with regard to the risks presented by pressure equipment, manufacturers shall, to protect the health and safety of consumers and other users, carry out sample testing of pressure equipment made available on the market, investigate, and, if necessary, keep a register of complaints of non-conforming pressure equipment and recalls of such equipment, and shall keep distributors informed of any such monitoring.

5. Manufacturers shall ensure that their pressure equipment bear a type, batch or serial number or other element allowing their identification, or, where the size or nature of the equipment does not allow it, that the required information is provided on the packaging or in a document accompanying the equipment.

6. Manufacturers shall indicate their name, registered trade name or registered trade mark, the postal address, and, if available, the website address at which they can be contacted on the pressure equipment or, where that is not possible, on their packaging or in a document accompanying the equipment. The address must indicate a single point at which the manufacturer can be contacted.

7. Manufacturers shall ensure that the pressure equipment referred to in Article 4(1) and (2), is accompanied by instructions and safety information in accordance with points 3.3 and 3.4 of Annex I, in a language which can be easily understood by consumers and other users, as determined by the Member State concerned. Such instructions and safety information shall be clear, understandable and intelligible.

Manufacturers shall ensure that the pressure equipment referred to in Article 4(3), is accompanied by instructions and safety information in accordance with Article 4(3), in a language which can be easily understood by consumers and other users, as determined by the Member State concerned. Such instructions and safety information shall be clear, understandable and intelligible.

8. Manufacturers who consider or have reason to believe that the pressure equipment which they have placed on the market is not in conformity with this Directive shall immediately take the necessary corrective measures necessary to bring that pressure equipment into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the pressure equipment presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the pressure equipment available on the market to that effect, giving details, in particular, of the noncompliance and of any corrective measures taken.

9. Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of the pressure equipment with this Directive, in a language which can be easily understood by that authority. That information and documentation may be provided in paper or electronic form. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by the pressure equipment which they have placed on the market.

Article 7 [Article R3 of Decision No 768/2008/EC]

Authorised representatives

1. A manufacturer may, by a written mandate, appoint an authorised representative.

The obligations laid down in Article 6(1) and the drawing up of technical documentation shall not form part of the authorised representative's mandate.

2. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:

- (a) keep the EU declaration of conformity and the technical documentation at the disposal of national surveillance authorities for 10 years after the pressure equipment has been placed on the market;

- (b) further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the pressure equipment;
- (c) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by pressure equipment covered by the authorised representative's mandate.

Article 8 [Article R4 of Decision No 768/2008/EC]

Obligations of importers

1. Importers shall place only compliant pressure equipment on the market.

2. Before placing on the market pressure equipment referred to in Article 4(1) and (2), importers shall ensure that the appropriate conformity assessment procedure in accordance with Article 14 has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the pressure equipment bears the CE marking and is accompanied by instructions and safety information in accordance with points 3.3 and 3.4 of Annex I, and that the manufacturer has complied with the requirements set out in Article 6(5) and (6).

Before placing on the market pressure equipment referred to in Article 4(3), importers shall ensure that the manufacturer has drawn up the technical documentation and that the pressure equipment is accompanied by adequate instructions for use and that the manufacturer has complied with the requirements set out in Article 6(5) and (6).

Where an importer considers or has reason to believe that pressure equipment is not in conformity with the essential safety requirements set out in Annex I, he shall not place the pressure equipment on the market until it has been brought into conformity. Furthermore, where the pressure equipment presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

3. Importers shall indicate their name, registered trade name or registered trade mark and the postal address at which they can be contacted on the pressure equipment or, where that is not possible, on its packaging or in a document accompanying the equipment. The contact details shall be in a language easily understood by users and market surveillance authorities.

4. Importers shall ensure that pressure equipment referred to in Article 4(1) and (2) is accompanied by instructions and safety information in accordance with points 3.3 and 3.4 of Annex I, in a language which can be easily understood by consumers and other users, as determined by the Member State concerned.

Importers shall ensure that the pressure equipment referred to in Article 4(3) is accompanied by instructions and safety information in a language which can be easily understood by consumers and other users, as determined by the Member State concerned.

5. Importers shall ensure that, while pressure equipment referred to in Article 4(1) and (2) is under their responsibility, storage or transport conditions do not jeopardise its compliance with the requirements set out in Annex I.

6. When deemed appropriate with regard to the risks presented by pressure equipment, importers shall, to protect the health and safety of consumers and other users, upon a duly justified request of the competent authorities, carry out sample testing of pressure equipment made available on the market, investigate, and, if necessary, keep a register of complaints, non-conforming pressure equipment and recalls of such equipment, and shall keep distributors informed of any such monitoring.

7. Importers who consider or have reason to believe that pressure equipment which they have placed on the market is not in conformity with this Directive shall immediately take the corrective measures necessary to bring that pressure equipment into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the pressure equipment presents a risk, importers shall immediately inform the competent national authorities of the Member States in which they made the pressure equipment available on the market to that effect, giving details, in particular, of the noncompliance and of any corrective measures taken.

8. Importers shall, for 10 years after the pressure equipment has been placed on the market, keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request.

9. Importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of pressure equipment in a language which can be easily understood by that authority. That information and documentation may be provided in paper or electronic form. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by pressure equipment which they have placed on the market.

Article 9 [Article R5 of Decision No 768/2008/EC]

Obligations of distributors

1. When making pressure equipment available on the market distributors shall act with due care in relation to the requirements of this Directive.

2. Before making pressure equipment referred to in Article 4(1) and (2) available on the market distributors shall verify that the pressure equipment bears the CE marking, that it is accompanied by the required documents and by instructions and safety information in accordance with points 3.3 and 3.4 of Annex I, in a language which can be easily understood by consumers and other users in the Member State in which the pressure equipment is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in Article 6(5) and (6) and Article 8(3).

Where a distributor considers or has reason to believe that pressure equipment is not in conformity with the essential safety requirements set out in Annex I, he shall not make the pressure equipment available on the market until it has been brought into conformity. Furthermore, where the pressure equipment presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.

Before making pressure equipment referred to in Article 4(3) available on the market distributors shall verify that the pressure equipment is accompanied by adequate instructions

for use, in a language which can be easily understood by consumers and other users in the Member State in which the pressure equipment is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in Article 6(5) and (6) and Article 8(3).

3. Distributors shall ensure that, while pressure equipment referred to in Article 4(1) and (2) is under their responsibility, storage or transport conditions do not jeopardise their/its compliance with the essential safety requirements set out in Annex I.

4. Distributors who consider or have reason to believe that pressure equipment which they have made available on the market is not in conformity with this Directive shall make sure that the corrective measures necessary to bring that equipment into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the pressure equipment presents a risk, distributors shall immediately inform the competent national authorities of the Member States in which they made the equipment available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

5. Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of pressure equipment. That information and documentation may be provided in paper or electronic form. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by the pressure equipment which they have made available on the market.

Article 10 [Article R6 of Decision No 768/2008/EC]

Cases in which obligations of manufacturers apply to importers and distributors

An importer or distributor shall be considered a manufacturer for the purposes of this Directive and he shall be subject to the obligations of the manufacturer under Article 6, where he places pressure equipment on the market under his name or trademark or modifies pressure equipment already placed on the market in such a way that compliance with the requirements of this Directive may be affected.

Article 11 [Article R7 of Decision No 768/2008/EC]

Identification of economic operators

Economic operators shall, on request, identify the following to the market surveillance authorities, for 10 years:

- (a) any economic operator who has supplied them with pressure equipment;
- (b) any economic operator to whom they have supplied pressure equipment.

Economic operators shall be able to present the information referred to in the first paragraph for a period of 10 years after they have been supplied with the pressure equipment and for a period of 10 years after they have supplied the pressure equipment.

CHAPTER 3

CONFORMITY AND CLASSIFICATION OF PRESSURE EQUIPMENT

↓ 97/23/EC

Article ~~5~~12 [Article R8 of Decision No 768/2008/EC]

Presumption of conformity

↓ new

1. Pressure equipment referred to in Article 4(1) and (2) which are in conformity with harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* shall be presumed to be in conformity with the essential safety requirements covered by those standards or parts thereof, referred to in Annex I.

↓ 97/23/EC (adapted)

~~1.2.~~ Member States shall regard pressure equipment and assemblies bearing the CE marking provided for in Article ~~15~~18 and the ~~EC~~ ☒ EU ☒ declaration of conformity provided for in ~~Annex VII Article 17~~ as conforming to all the provisions of this Directive, including the conformity assessment provided for in Article 10.

↓ 97/23/EC

~~2. Pressure equipment and assemblies which conform to the national standards transposing the harmonized standards the reference numbers of which have been published in the Official Journal of the European Communities shall be presumed to conform to the essential requirements referred to in Article 3. Member States shall publish the reference numbers of the national standards referred to above.~~

~~3. Member States shall ensure that appropriate measures are taken to enable both sides of industry to have an input at national level in the process of preparing and monitoring the harmonized standards.~~

↓ 97/23/EC (adapted)

~~4.3.~~ The materials used for the manufacture of pressure equipment ~~conforming~~ ☒ which are in conformity ☒ with European approvals for materials, the references of which have been published in the *Official Journal of the European Communities* ☒ Union in accordance with Article 15(4), ☒ shall be presumed to ~~conform to~~ ☒ be in conformity with ☒ the applicable essential ☒ safety ☒ requirements ~~of~~ ☒ set out in ☒ Annex I.

Classification of pressure equipment

1. Pressure equipment referred to in Article ~~3~~4(1) shall be classified by category in accordance with Annex II, according to ascending level of ~~hazard~~ ☒ risk ☒.

For the purposes of such classification fluids shall be divided into ☒ the following ☒ two groups: ~~in accordance with 2.1 and 2.2.~~

↓ 97/23/EC

~~2.1. Group 1 comprises dangerous fluids. A dangerous fluid is a substance or preparation covered by the definitions in Article 2 (2) of Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances⁴³.~~

~~Group 1 comprises fluids defined as:~~

~~explosive,~~

~~extremely flammable,~~

~~highly flammable,~~

~~flammable (where the maximum allowable temperature is above flashpoint),~~

~~very toxic,~~

~~toxic,~~

~~oxidizing.~~

↓ new

(a) group 1 that comprises fluids consisting of substances and mixtures, as defined in points (7) and (8) of Article 2 of Regulation (EC) No 1272/2008, that are classified as hazardous in accordance with the following physical or health hazard classes laid down in Parts 2 and 3 of Annex I to that Regulation:

- (i) unstable explosives or explosives of Divisions 1.1, 1.2, 1.3, 1.4 and 1.5;
- (ii) flammable gases, category 1 and 2;
- (iii) oxidising gases, category 1;
- (iv) flammable liquids, categories 1 and 2;

⁴³ OJ No 196, 16. 8. 1967, p. 1. Directive as last amended by Commission Directive 94/69/EC (OJ No L 381, 31. 12. 1994, p. 1).

- (v) flammable liquids, category 3 where the maximum allowable temperature is above the flashpoint;
- (vi) flammable solids, category 1 and 2;
- (vii) self-reactive substances and mixtures, type A to F;
- (viii) pyrophoric liquids, category 1;
- (ix) pyrophoric solids, category 1;
- (x) substances and mixtures which in contact with water emit flammable gases, category 1, 2 and 3;
- (xi) oxidising liquids, category 1, 2 and 3;
- (xii) oxidising solids, category 1, 2 and 3;
- (xiii) organic peroxides types A to F;
- (xiv) acute oral toxicity: category 1 and 2;
- (xv) acute dermal toxicity: category 1 and 2;
- (xvi) acute inhalation toxicity: category 1, 2 and 3;
- (xvii) specific target organ toxicity – single exposure: category 1.

↓ 97/23/EC (adapted)

~~2.2.(b)~~ Group 2 ☒ that ☒ comprises all other fluids not referred to in ~~2.1~~ point (a).

↓ 97/23/EC

~~3.2.~~ Where a vessel is composed of a number of chambers, it shall be classified in the highest category applicable to the individual chambers. Where a chamber contains several fluids, classification shall be on the basis of the fluid which requires the highest category.

↓ 97/23/EC (adapted)

Article ~~10~~14

Conformity assessment

~~1.1. Before placing pressure equipment on the market, the manufacturer shall subject each item of equipment to one of the conformity assessment procedures described in Annex III, according to the conditions given in this Article.~~

~~1.2.1.~~ The conformity assessment procedures to be applied to an item of pressure equipment with a view to affixing the CE marking shall be determined by the category, as defined ☒ set out ☒ in Article ~~9~~13, in which the equipment is classified.

1.3.2. The conformity assessment procedures to be applied for the various categories are as follows $\langle \boxtimes \rangle$ the following $\langle \boxtimes \rangle$:

↓ 97/23/EC

(a) category I:

- Module A

(b) category II:

- Module A~~±~~2
- Module D1
- Module E1

(c) category III:

↓ 97/23/EC (adapted)

- Module B~~±~~ $\langle \boxtimes \rangle$ (design type) $\langle \boxtimes \rangle$ + D
- Module B~~±~~ $\langle \boxtimes \rangle$ (design type) $\langle \boxtimes \rangle$ + F
- Module B $\langle \boxtimes \rangle$ (combination of production type and design type) $\langle \boxtimes \rangle$ + E
- Module B $\langle \boxtimes \rangle$ (combination of production type and design type) $\langle \boxtimes \rangle$ + C~~±~~2

↓ 97/23/EC

- Module H

(d) category IV:

↓ 97/23/EC (adapted)

- Module B $\langle \boxtimes \rangle$ (combination of production type and design type) $\langle \boxtimes \rangle$ + D
- Module B $\langle \boxtimes \rangle$ (combination of production type and design type) $\langle \boxtimes \rangle$ + F

↓ 97/23/EC (adapted)

- Module G
- Module H1

$\langle \boxtimes \rangle$ The conformity assessment procedures are set out in Annex III. $\langle \boxtimes \rangle$

1.4.3. Pressure equipment shall be subjected to one of the conformity assessment procedures which may be chosen by the manufacturer among those laid down for the category in which it

is classified. The manufacturer may also choose to apply one of the procedures which apply to a higher category, if available.

~~1.5.4.~~ In the framework of quality assurance procedures for ☒ pressure ☐ equipment in categories III and IV referred to in Article ~~34(1)(a)(i), section 1.1 (a), section 1~~ first indent of ~~Article 4(1)(ba)(ii) and 3 Article 4(1)(b) section 1.2~~, the notified body shall, when performing unexpected visits, take a sample of equipment from the manufacturing or storage premises in order to perform, or have performed, the final assessment as referred to in Annex I, ~~section point~~ 3.2.2. To this end, the manufacturer shall inform the notified body of the intended schedule of production. The notified body shall carry out at least two visits during the first year of manufacturing. The frequency of subsequent visits shall be determined by the notified body on the basis of the criteria set out in ~~section point~~ 4.4 of the relevant modules.

~~1.6.5.~~ In the case of one-off production of vessels and ☒ pressure ☐ equipment in Category III referred to in Article ~~34(1)(b), section 1.2~~ under the module H procedure, the notified body shall perform or have performed the final assessment, as referred to in ~~Annex I, section point~~ 3.2.2 of Annex I, for each unit. To this end, the manufacturer shall communicate the intended schedule of production to the notified body.

↓ 97/23/EC (adapted)

~~2.6.~~ Assemblies referred to in Article ~~34(2)~~ shall be subjected to a global conformity assessment procedure comprising ☒ the following assessments ☐ :

↓ 97/23/EC (adapted)

⇒ new

(a) ☒ the ☐ assessment of each item of pressure equipment making up the assembly and referred to in Article ~~34(1)~~ which has not been previously subjected to a conformity assessment procedure and to a separate CE marking; the assessment procedure shall be determined by the category of each item of equipment;

(b) the assessment of the integration of the various components of the assembly as referred to in ~~sections points~~ 2.3, 2.8 and 2.9 of Annex I which shall be determined by the highest category applicable to the equipment concerned other than that applicable to any safety accessories;

(c) the assessment of the protection of an assembly against exceeding the permissible operating limits as referred to in ~~sections points~~ 2.10 and 3.2.3 of Annex I shall be conducted in the light of the highest category applicable to the items of equipment to be protected.

~~3.7.~~ By way of derogation from paragraphs 1 and 2, the competent authorities may, where justified, allow the ~~placing~~ ⇒ making available ⇐ on the market and putting into service in the territory of the Member State concerned of individual pressure equipment items and assemblies referred to in Article ~~12(2)~~, in respect of which the procedures referred to in paragraphs 1 and 2 of this Article have not been applied and the use of which is in the interests of experimentation.

↓ 97/23/EC (adapted)

4. Records and correspondence relating to conformity assessment shall be drawn up in the official language(s) of the ~~Community~~ ☒ Union ☒ which may be determined ~~in accordance with the Treaty~~ by the Member State where the body responsible for carrying out these procedures is established, or in a language accepted by that body.

↓ 97/23/EC (adapted)

Article ~~11~~15

European approval for materials

1. European approval for materials, ~~as defined in Article 1, section 2.9,~~ shall be issued at the request of one or more manufacturers of materials or equipment, by one of the notified bodies referred to in Article ~~1220~~ specifically designated for that task. The notified body shall determine and perform, or arrange for the performance of, the appropriate inspections and tests to certify the conformity of the types of material with the corresponding requirements of this Directive. ~~In the case of materials recognized as being safe to use before 29 November 1999, the notified body shall take account of the existing data when certifying such conformity.~~

↓ 97/23/EC (adapted)

⇒ new

2. Before issuing ☒ a ☒ European approval for materials, the notified body shall ~~inform~~ ☒ notify ☒ the Member States and the Commission ~~by sending them~~ the appropriate information. Within three months, a Member State or the Commission may ~~refer the matter to the Standing Committee set up by Article 5 of Directive 83/189/EEC,~~ ⇒ provide comments ⇐ giving its reasons. ~~In that case, the Committee shall issue an opinion as a matter of urgency.~~

The notified body ~~shall~~ ☒ may ☒ issue the European approval for materials taking into account, ~~where appropriate, the opinion of the Committee and~~ the comments submitted.

↓ 97/23/EC (adapted)

3. A copy of the European approval for ~~pressure equipment~~ materials shall be sent to the Member States, the notified bodies and the Commission.

↓ 97/23/EC (adapted)

4. ☒ When the European approval for materials satisfies the requirements which it covers and which are set out in Annex I, ☒ ~~The~~ Commission shall publish ☒ the references of that approval. ☒ ~~and~~ ☒ The Commission shall ☒ keep up to date a list of ☒ such ☒ European approvals ~~for materials~~ in the *Official Journal of the European Communities* ☒ Union ☒.

↓ 97/23/EC (adapted)
→₁ Corrigendum, OJ L 265,
27.9.1997, p. 110

5. The notified body which issued the European approval for ~~pressure equipment~~ materials shall withdraw that approval if it finds that it should not have been →₁ issued or if the type ← of materials is covered by a harmonised standard. It shall immediately inform the other Member States, the notified bodies and the Commission of any withdrawal of an approval.

↓ new

6. When a Member State or the Commission considers that a European approval for materials whose references have been published in the *Official Journal of the European Union*, does not entirely satisfy the essential safety requirements which it covers and which are set out in Annex I, the Commission shall decide by implementing acts whether to withdraw the references of that European approval for materials from the *Official Journal of the European Union*.

The implementing acts referred to in the first subparagraph shall be adopted in accordance with the examination procedure referred to in Article 39(3).

↓ 97/23/EC (adapted)
⇒ new

Article ~~14~~16

User inspectorates

1. By way of derogation from the provisions relating to the tasks carried out by the notified bodies, Member States may authorize ~~in~~ ☒ on ☒ their territory the ~~placing~~ ⇒ making available ⇐ on the market, and the putting into service by users, of pressure equipment ~~or assemblies referred to in Article 1~~ of which conformity with the essential ☒ safety ☒ requirements has been assessed by a user inspectorate designated in accordance with ~~the criteria referred to in paragraph 8~~7.

↓ 97/23/EC (adapted)

~~3.2.~~ Pressure equipment ~~and assemblies~~ the conformity of which has been assessed by a user inspectorate shall not bear the CE marking.

↓ 97/23/EC (adapted)

~~4.3.~~ The pressure equipment ~~and assemblies~~ referred to in paragraph 1 may be used only in establishments operated by the group of which the inspectorate is part. The group shall apply a common safety policy as regards the technical specifications for the design, manufacture, inspection, maintenance and use of pressure equipment ~~and assemblies~~.

↓ 97/23/EC (adapted)

~~54.~~ The user inspectorates shall act exclusively for the group of which they are part.

~~65.~~ The conformity assessment procedures applicable by user inspectorates shall be modules ~~A~~12~~~~, ~~C~~12~~~~, F and G, as described ~~☒~~ set out ~~☒~~ in Annex III.

↓ 97/23/EC (adapted)

~~76.~~ Member States shall ~~inform~~ ~~☒~~ notify ~~☒~~ the other Member States and the Commission which user inspectorates they have authorised, the tasks for which they have been designated and, for each inspectorate, a list of the establishments satisfying the provisions of paragraph ~~43~~.

~~87.~~ In designating the user inspectorates, the Member States shall apply the ~~criteria listed~~ ~~☒~~ requirements set out ~~☒~~ in ~~Annex V~~ Article 25 and ensure that the group of which the inspectorate is part applies the criteria referred to in the second sentence of paragraph ~~43~~.

↓ 97/23/EC

~~9. A Member State that has authorized a user inspectorate shall withdraw that authorization if it finds that the user inspectorate no longer meets the criteria referred to in paragraph 8. It shall inform the other Member States and the Commission thereof.~~

~~10. The effects of this Article shall be monitored by the Commission and evaluated three years after the date specified in Article 20 (3). To this end, Member States shall forward to the Commission any useful information on the implementation of this Article. If necessary the evaluation shall be accompanied by a proposal for amendment of the Directive.~~

↓ new

Article 17 [Article R10 of Decision No 768/2008/EC]

EU declaration of conformity

1. The EU declaration of conformity shall state that the fulfilment of essential safety requirements set out in Annex I has been demonstrated.

2. The EU declaration of conformity shall have the model structure set out in Annex III and shall contain the elements specified in the relevant conformity assessment procedures set out in Annex II and shall be continuously updated. It shall be translated into the language or languages required by the Member State in whose market the pressure equipment is placed or made available on the market.

3. Where pressure equipment is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts. That declaration shall contain the identification of the acts concerned including the publication references.

4. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the pressure equipment with the requirements laid down in this Directive.

Article 18 [Article R11 of Decision No 768/2008/EC]

General principles of the CE marking

The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

↓ 97/23/EC (adapted)

Article ~~15~~19 [Article R12 of Decision No 768/2008/EC]

☒ Rules and conditions for affixing the ☒ CE marking

↓ 97/23/EC

~~1. The CE marking consists of the initials «CE» in accordance with the model in Annex VI.~~

~~The CE marking shall be accompanied by the identification number, as referred to in Article 12 (1), of the notified body involved at the production control phase.~~

↓ 97/23/EC (adapted)

⇒ new

~~2.1. The CE marking shall be affixed in a visible, easily legible and indelible fashion~~
☒ visibly, legibly and indelibly ☒ to ☒ any of the following: ☒

(a) each item of pressure equipment referred to in Article ~~34~~(1), or

(b) assembly referred to in Article ~~34~~(2).

~~which is~~ ☒ The item or assembly referred to in points (a) and (b) of the first subparagraph shall be ☒ complete or is ☒ shall be ☒ in a state permitting final assessment as described in ~~section~~ point 3.2 of Annex I ⇒ , or to its data plate. Where the affixing of the CE marking is not possible or not warranted on account of the nature of the equipment or assembly, it shall be affixed to the packaging and to the accompanying documents ⇐.

~~3.2.~~ It is not necessary for the CE marking to be affixed to each individual item of pressure equipment making up an assembly ~~as referred to in Article 3 (2)~~. Individual items of pressure equipment already bearing the CE marking when incorporated into the assembly shall continue to bear that marking.

~~4. Where the pressure equipment or assembly is subject to other Directives covering other aspects which provide for the affixing of the CE marking, the latter shall indicate that the pressure equipment or assembly in question is also presumed to conform to the provisions of those other Directives.~~

~~However, should one or more of those Directives allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate conformity only with the Directives applied by the manufacturer. In this case, the particulars of the said Directives, as published in the *Official Journal of the European Communities*, must be given in the documents, notices or instructions required by the Directives and accompanying the pressure equipment or assembly.~~

~~5. The affixing of markings on pressure equipment or assemblies which are likely to mislead third parties as to the meaning or form of the CE marking shall be prohibited. Any other marking may be affixed to pressure equipment or assemblies provided that the visibility and legibility of the CE marking is not thereby reduced.~~

3. The CE marking shall be affixed before the item of pressure equipment or the assembly is placed on the market.

4. The CE marking shall be followed by the identification number of the notified body, where that body is involved in the production control phase.

The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the manufacturer or his authorised representative.

5. The CE marking and, where applicable, the identification number referred to in paragraph 4 may be followed by any other mark indicating a special risk or use.

CHAPTER 4

NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

~~Article 12~~

Notified bodies

~~1. Member States shall notify the Commission and the other Member States of the bodies which they have appointed to carry out the procedures referred to in Article 10 and Article 11, together with the specific tasks which those bodies have been appointed to carry out and the identification numbers assigned to them beforehand by the Commission.~~

~~The Commission shall publish in the *Official Journal of the European Communities* a list of the notified bodies, with their identification numbers and the tasks for which they have been notified. The Commission shall ensure that this list is kept up to date.~~

~~2. Member States shall apply the criteria set out in Annex IV for the designation of bodies. Bodies meeting the criteria laid down in the relevant harmonized standards shall be presumed to fulfil the corresponding criteria in Annex IV.~~

~~3. A Member State which has notified a body must withdraw such notification if it finds that the body no longer meets the criteria referred to in paragraph 2.~~

~~It shall forthwith inform the other Member States and the Commission of any such withdrawal of a notification.~~

~~Article 13~~

Recognized third-party organizations

~~1. Member States shall notify the Commission and the other Member States of the third-party organizations which they have recognized for the purposes of the tasks referred to in Annex I, sections 3.2.2 and 3.1.3.~~

~~The Commission shall publish in the *Official Journal of the European Communities* a list of the recognized organizations with the tasks for which they have been recognized. The Commission shall ensure that this list is kept up to date.~~

~~2. Member States shall apply the criteria set out in Annex IV for the recognition of organizations. Organizations meeting the criteria laid down in the relevant harmonized standards shall be presumed to fulfil the corresponding criteria in Annex IV.~~

~~3. A Member State which has recognized an organization must withdraw such recognition if it finds that the organization no longer meets the criteria referred to in paragraph 2.~~

~~It shall forthwith inform the other Member States and the Commission of any such withdrawal of a recognition.~~

↓ new

Article 20 [Article R13 of Decision No 768/2008/EC]

Notification

Member States shall notify the Commission and the other Member States of the notified bodies and the user inspectorates authorised to carry out third-party conformity assessment tasks in accordance with Article 15, Article 16 or Annex III and of the third-party organisations they have recognised, for the purposes of the tasks referred to in points 3.1.2 and 3.1.3 of Annex I.

Notifying authorities

1. Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, recognised third-party organisations and user inspectorates, including compliance with Article 26.
2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.
3. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 to a body which is not a governmental entity, that body shall be a legal entity and shall comply *mutatis mutandis* with the requirements laid down in Article 22(1) to (6). In addition it shall have arrangements to cover liabilities arising out of its activities.
4. The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.

Requirements relating to notifying authorities

1. A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.
2. A notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.
3. A notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.
4. A notifying authority shall not offer or provide any activities that conformity assessment bodies perform or consultancy services on a commercial or competitive basis.
5. A notifying authority shall safeguard the confidentiality of the information it obtains.
6. A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

Information obligation on notifying authorities

Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, recognised third-party organisations and user inspectorates, and of any changes thereto.

The Commission shall make that information publicly available.

Requirements relating to notified bodies and recognised third-party organisations

1. For the purposes of notification, a notified body or recognised third party organisation shall meet the requirements laid down in paragraphs 2 to 11.

2. A conformity assessment body shall be established under national law and have legal personality.

3. A conformity assessment body shall be a third-party body independent of the organisation or the pressure equipment it assesses.

A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of pressure equipment which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.

4. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the pressure equipment which they assess, nor the representative of any of those parties. This shall not preclude the use of assessed pressure equipment that are necessary for the operations of the conformity assessment body or the use of such equipment for personal purposes.

A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of that pressure equipment, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

5. Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and

inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

6. A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Article 15, Annex III or points 3.1.2 and 3.1.3 of Annex I and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

At all times and for each conformity assessment procedure and each kind or category of pressure equipment in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary:

- (a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;
- (b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a conformity assessment body and other activities;
- (c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.

It shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.

7. The personnel responsible for carrying out conformity assessment activities shall have the following:

- (a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;
- (b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;
- (c) appropriate knowledge and understanding of the essential safety requirements set out in Annex I, of the applicable harmonised standards and of the relevant provisions of Union harmonisation legislation and of national legislation;
- (d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

8. The impartiality of the conformity assessment bodies, their top level management and of the assessment personnel shall be guaranteed.

The remuneration of the top level management and assessment personnel of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

9. Conformity assessment bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.

10. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under Article 15, Annex III or under points 3.1.2 and 3.1.3 of Annex I or any provision of national law giving effect to them, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.

11. Conformity assessment bodies shall participate in, or ensure that their assessment personnel are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under the relevant Union harmonisation legislation and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

Article 25

Requirements relating to user inspectorates

1. For the purposes of notification, a user inspectorate shall meet the requirements laid down in paragraphs 2 to 11.

2. A user inspectorate shall be established under national law and have legal personality.

3. A user inspectorate shall be organisationally identifiable and have reporting methods within the group of which it is part which ensure and demonstrate its impartiality.

4. A user inspectorate, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the pressure equipment which they assess, nor the authorised representative of any of those parties. This shall not preclude the use of assessed pressure equipment that is necessary for the operations of the user inspectorate or the use of such equipment for personal purposes.

A user inspectorate, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of that pressure equipment, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

5. User inspectorates and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements,

particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

6. A user inspectorate shall be capable of carrying out all the conformity assessment tasks assigned to it by Article 16 and in relation to which it has been notified, whether those tasks are carried out by the user inspectorate itself or on its behalf and under its responsibility.

At all times and for each conformity assessment procedure and each kind or category of pressure equipment in relation to which it has been notified, the user inspectorate shall have at its disposal the necessary:

- (a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;
- (b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a user inspectorate and other activities;
- (c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.

It shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.

7. The personnel responsible for carrying out conformity assessment activities shall have the following:

- (a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;
- (b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;
- (c) appropriate knowledge and understanding of the essential safety requirements set out in Annex I, of the applicable harmonised standards and of the relevant provisions of Union harmonisation legislation and of national legislation;
- (d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

8. The impartiality of the user inspectorates, their top level management and of the assessment personnel shall be guaranteed. User inspectorates must not engage in any activities that might conflict with its independence of judgement and integrity in relation to its inspection activities.

The remuneration of the top level management and assessment personnel of a user inspectorate shall not depend on the number of assessments carried out or on the results of those assessments.

9. User inspectorates shall take out liability insurance unless liability is assumed by the group of which they are part.

10. The personnel of user inspectorates shall observe professional secrecy with regard to all information obtained in carrying out their tasks under Article 16 or any provision of national law giving effect to them, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.

11. User inspectorates shall participate in, or ensure that their assessment personnel are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under the relevant Union harmonisation legislation and apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

Article 26 [Article R18 of Decision No 768/2008/EC]

Presumption of conformity

Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* it shall be presumed to comply with the requirements set out in Articles 24 or 25 in so far as the applicable harmonised standards cover those requirements.

Article 27 [Article R20 of Decision No 768/2008/EC]

Subsidiaries of and subcontracting by notified bodies and recognised third-party organisations

1. Where a notified body or a recognised third-party organisation subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 24 and shall inform the notifying authority accordingly.

2. Notified bodies and recognised third-party organisations shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.

3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.

4. Notified bodies and recognised third-party organisations shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Article 15, Annex III or points 3.1.2 and 3.1.3 of Annex I.

Application for notification

1. A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.
2. That application shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the pressure equipment for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 24 or 25.
3. Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 24 or 25.

Notification procedure

1. Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article 24 or 25.
2. They shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.
3. The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and the pressure equipment concerned and the relevant attestation of competence.
4. Where a notification is not based on an accreditation certificate as referred to in Article 28(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 24 or 25.
5. The body concerned may perform the activities of a notified body, a recognised third-party organisation or a user inspectorate only where no objections are raised by the Commission or the other Member States within two weeks of a notification where an accreditation certificate is used or within two months of a notification where accreditation is not used.

Only such a body shall be considered a notified body, a recognised third-party organisation or a user inspectorate for the purposes of this Directive.
6. The Commission and the other Member States shall be notified of any subsequent relevant changes to the notification.

Identification numbers and lists of notified bodies

1. The Commission shall assign an identification number to a notified body.

It shall assign a single such number even where the body is notified under several Union acts.

2. The Commission shall make publicly available the list of the notified bodies under this Directive, including the identification numbers that have been allocated to them and the activities for which they have been notified.

The Commission shall ensure that that list is kept up to date.

Article 31

Lists of recognised third-party organisations and user inspectorates

The Commission shall make publicly available the list of the recognised third-party organisations and of the user inspectorates under this Directive and the tasks for which they have been recognised.

The Commission shall ensure that that list is kept up to date.

Article 32 [Article R25 of Decision No 768/2008/EC]

Changes to notifications

1. Where a notifying authority has ascertained or has been informed that a notified body or a recognised third-party organisation no longer meets the requirements laid down in Article 24 or that it is failing to fulfil its obligations, the notifying authority shall, as appropriate, restrict, suspend or withdraw the notification, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.

Where a notifying authority has ascertained or has been informed that a user inspectorate no longer meets the requirements laid down in Article 25, or that it is failing to fulfil its obligations, the notifying authority shall as appropriate, restrict, suspend or withdraw the notification, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.

2. In the event of restriction, suspension or withdrawal of notification, or where the notified body, the recognised third-party organisation or the user inspectorate has ceased its activity, the notifying Member State shall take appropriate steps to ensure that the files of that body are either processed by another notified body, recognised third-party organisation or user inspectorate, or kept available for the responsible notifying and market surveillance authorities at their request.

Challenge of the competence of notified bodies, recognised third party organisations and user inspectorates

1. The Commission shall investigate all cases where it doubts, or doubt is brought to its attention regarding, the competence of a notified body, a recognised third-party organisation or a user inspectorate, or the continued fulfilment by a notified body, a recognised third-party organisation or a user inspectorate of the requirements and responsibilities to which it is subject.

2. The notifying Member State shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the body concerned.

3. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.

4. Where the Commission ascertains that a notified body, a recognised third-party organisation or a user inspectorate does not meet or no longer meets the requirements for its notification, it shall adopt an implementing act requesting the notifying Member State to take the necessary corrective measures, including withdrawal of notification if necessary.

The implementing act referred to in the first subparagraph shall be adopted in accordance with the advisory procedure referred to in Article 39(2).

Operational obligations of notified bodies, user inspectorates and recognised third party organisations

1. Notified bodies, user inspectorates and recognised third-party organisations shall carry out conformity assessments in accordance with the conformity assessment tasks provided for in Article 15, Article 16, Annex III or in points 3.1.2 and 3.1.3 of Annex I.

2. Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators.

Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the pressure equipment or assembly technology in question and the mass or serial nature of the production process.

In so doing they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the pressure equipment with the provisions of this Directive.

3. Where a conformity assessment body finds that essential safety requirements set out in Annex I or corresponding harmonised standards have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a conformity certificate.

4. Where, in the course of the monitoring of conformity following the issue of a certificate, a conformity assessment body finds that pressure equipment no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate if necessary.

5. Where corrective measures are not taken or do not have the required effect, the conformity assessment body shall restrict, suspend or withdraw any certificates, as appropriate.

Article 35

Appeal against decisions of notified bodies, recognised third party organisations and user inspectorates

Member States shall ensure that an appeal procedure against decisions of notified bodies, recognised third-party organisations or user inspectorates is available.

Article 36 [Article R28 of Decision No 768/2008/EC]

Information obligation on notified bodies, recognised third party organisations and user inspectorates

1. Notified bodies, recognised third-party organisations and user inspectorates shall inform the notifying authority of the following:

- (a) any refusal, restriction, suspension or withdrawal of a certificate;
- (b) any circumstances affecting the scope of and conditions for notification;
- (c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;
- (d) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.

2. Notified bodies, recognised third-party organisations and user inspectorates shall provide the other bodies notified under this Directive carrying out similar conformity assessment activities covering the same pressure equipment with relevant information on issues relating to negative and, on request, positive conformity assessment results.

Article 37 [Article R29 of Decision No 768/2008/EC]

Exchange of experience

The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy.

Coordination of notified bodies, recognized third-party organisations and user inspectorates

The Commission shall ensure that appropriate coordination and cooperation between the conformity assessment bodies notified under this Directive are put in place and properly operated in the form of a sectoral group or groups of conformity assessment bodies.

Member States shall ensure that the conformity assessment bodies notified by them participate in the work of that or those group or groups, directly or by means of designated representatives.

↓ 97/23/EC

~~Article 8~~

~~Safeguard clause~~

~~1. Where a Member State ascertains that pressure equipment or assemblies referred to in Article 1, bearing the CE marking and used in accordance with their intended use are liable to endanger the safety of persons and, where appropriate, domestic animals or property, it shall take all appropriate measures to withdraw such equipment or assemblies from the market, prohibit the placing on the market, putting into service or use thereof, or restrict free movement thereof.~~

~~The Member State shall immediately inform the Commission of any such measure, indicating the reasons for its decision and, in particular, whether non-conformity is due to:~~

~~(a) — failure to satisfy the essential requirements referred to in Article 3;~~

~~(b) — incorrect application of the standards referred to in Article 5 (2);~~

~~(c) — shortcomings in the standards referred to in Article 5 (2);~~

~~(d) — shortcomings in the European approval of pressure equipment materials as referred to in Article 11.~~

~~2. The Commission shall enter into consultation with the parties concerned without delay. Where the Commission considers, after this consultation, that the measure is justified, it shall immediately so inform the Member State which took the initiative and the other Member States.~~

~~Where the Commission considers, after this consultation, that the measure is unjustified, it shall immediately so inform the Member State which took the initiative and the manufacturer, or his authorized representative established within the Community. Where the decision referred to in paragraph 1 is based on a shortcoming in the standards or in European approvals for materials and where the Member State at the origin of the decision maintains its position the Commission shall immediately inform the Committee referred to in Article 6 in order to initiate the procedure referred to in the first paragraph of Article 6.~~

~~3. Where pressure equipment or an assembly which does not comply bears the CE marking, the competent Member State shall take appropriate action against the person(s) having affixed the CE marking and shall so inform the Commission and the other Member States.~~

~~4. The Commission shall ensure that the Member States are kept informed of the progress and outcome of this procedure.~~

~~Article 16~~

~~Unduly affixed CE marking~~

~~Without prejudice to Article 8:~~

~~(a) where a Member State establishes that the CE marking has been affixed unduly, the manufacturer, or his authorized representative established within the Community, shall be obliged to make the product conform as regards the provisions concerning the CE marking and to end the infringement under the conditions imposed by the Member State;~~

~~(b) should non-conformity persist, the Member State must take all appropriate measures to restrict or prohibit the placing on the market of the product in question or to ensure that it is withdrawn from the market in accordance with the procedures laid down in Article 8.~~

~~Article 17~~

~~Member States shall take appropriate measures in order to encourage the authorities responsible for implementing this Directive to cooperate with each other and provide each other and the Commission with information in order to assist the functioning of this Directive.~~

~~Article 18~~

~~Decisions entailing refusal or restriction~~

~~Any decision taken pursuant to this Directive which restricts the placing on the market and the putting into service or requires the withdrawal from the market of pressure equipment or assemblies shall state the exact grounds on which it is based. Such decision shall be notified forthwith to the party concerned, who shall at the same time be informed of the legal remedies available to him under the laws in force in the Member State concerned and of the time limits to which such remedies are subject.~~

↓ 97/23/EC (adapted)

CHAPTER 5

⊠ COMMITTEE PROCEDURE AND DELEGATED ACTS ⊠

Article ~~7~~39

Committee ~~on Pressure Equipment~~ ⊠ procedure ⊠

↓ 1882/2003 Art. 1 and Annex I.13 (adapted)
⇒ new

21. The Commission shall be assisted by ~~a standing committee (hereinafter referred to as «the Committee»)~~ ⊠ the Committee on Pressure Equipment established by Directive 97/23/EC ⊠. ⇒ That committee shall be a committee within the meaning of Regulation (EU) No 182/2011. ⇐

~~The Committee shall draw up its rules of procedure.~~

~~3=2.~~ Where reference is made to this paragraph, Article ~~4,~~ Articles 3 and 7 of Decision 1999/468/EC⁴⁴ ⇒ of Regulation (EU) No 182/2011 ⇐ shall apply, ~~having regard to the provisions of Article 8 thereof.~~

↓ new

3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Where the opinion of the committee is to be obtained by written procedure, that procedure shall be terminated without result when, within the time-limit for delivery of the opinion, the chair of the committee so decides or a simple majority of committee members so request.

↓ 97/23/EC

~~4. The Committee may furthermore examine any other matter relating to the implementation and practical application of this Directive and raised by its chairman either on his own initiative or at the request of a Member State.~~

⁴⁴ Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).

↓ new

Article 40

Amendments of Annexes

The Commission shall be empowered to adopt delegated acts in accordance with Article 41 concerning the reclassification of pressure equipment when it has any of the following considerations:

↓ 97/23/EC

~~1. The Commission may take any appropriate measure to implement the following provisions:~~

~~Where a Member State considers that, for very serious safety reasons,~~

↓ 97/23/EC (adapted)

- (a) an item or family of pressure equipment referred to in Article ~~34~~(3) should be subject to the requirements of Article ~~34~~(1)~~);~~ ~~or~~
- (b) an assembly or family of assemblies referred to in Article ~~34~~(3) should be subject to the requirements of Article ~~34~~(2)~~);~~ ~~or~~

↓ 97/23/EC

- (c) an item or family of pressure equipment should be classified, by way of derogation from the requirements of Annex II, in another category~~;~~

~~it shall submit a duly substantiated request to the Commission and ask it to take the necessary measures. Those measures shall be adopted in accordance with the procedure laid down in paragraph 3.~~

↓ new

Article 41

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The delegation of power referred to in Article 40 shall be conferred for an indeterminate period of time from 1 June 2015.

3. The delegation of powers referred to in Article 40 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the

delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act adopted pursuant to Article 40 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

CHAPTER 6

TRANSITIONAL AND FINAL PROVISIONS

Article 42

Penalties

Member States shall lay down rules on penalties applicable to infringements by economic operators of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. Such rules may include criminal penalties for serious infringements.

The penalties referred to in the first subparagraph must be effective, proportionate and dissuasive.

↓ 97/23/EC (adapted)
⇒ new

Article 43

⊠ Transitional provisions ⊠

31. Member States ~~must permit~~ ⊠ shall not impede ⊠ the ~~placing on the market~~ ⇒ putting into service ⇐ of pressure equipment and assemblies which comply with the regulations in force in their territory at the date of application of ~~this Directive~~ 97/23/EC ⇒ and were placed on the market ⇐ until 29 May 2002, ~~and permit such equipment and assemblies to be put into service beyond that date.~~

↓ new

2. Member States shall not impede the making available on the market and/or the putting into service of pressure equipment covered by Directive 97/23/EC which are in conformity with that Directive and which were placed on the market before 1 June 2015.

3. Certificates issued under Directive 97/23/EC shall be valid under this Directive.

↓ 97/23/EC (adapted)

Article ~~20~~44

Transposition ~~and transitional provisions~~

1. ~~Before 29 May 1999~~ Member States shall adopt and publish ☒ by 1 March 2015 at the latest, ☒ the laws, regulations and administrative provisions necessary to comply with ~~this Directive~~ ☒ Articles 2(15) to (31), 6, 7, 8, 9, 10, 11, 12, 17, 18, 19(3) to (5), 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 42, 43 and Annexes III and IV ☒. They shall forthwith ~~inform~~ ☒ communicate to ☒ the Commission ~~thereof~~ ☒ the text of those measures ☒ .

~~Member States~~ ☒ They ☒ shall apply ~~such~~ ☒ those measures ☒ ~~provisions as from 29 November 1999~~ ☒ 1 June 2015 ☒ .

When Member States adopt ~~these~~ ☒ those ☒ measures ~~referred to in the first subparagraph,~~ they shall contain a reference to this Directive or ~~shall~~ be accompanied by such reference on the occasion of their official publication. ~~The methods of making such reference shall be laid down by Member States.~~ ☒ They shall also include a statement that references in existing laws, regulations and administrative provisions to Directive 97/23/EC shall be construed as references to this Directive. Member States shall determine how such reference is to be made and how that statement is to be formulated. ☒

2. Member States shall communicate to the Commission the ~~texts~~ of the ☒ main ☒ provisions of national law which they adopt in the field governed by this Directive.

Article ~~19~~ 45

Repeal

~~Article 22 of Directive 76/767/EEC shall cease to apply as from 29 November 1999 in respect of pressure equipment and assemblies covered by this Directive.~~

↓

Directive 97/23/EC, as amended by the acts listed in Annex V, Part A, is repealed with effect from 1 June 2015, without prejudice to the obligations of the Member States relating to the

time-limits for transposition into national law and application of that Directive, set out in Part B of Annex V.

References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex VI.

Article 46

Entry into force

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Articles 1, 2(1) to (14), 3, 4, 5, 13, 14, 15, 16, 19(1) and (2), 39, 40 and 41 and Annexes I and II shall apply from 1 June 2015.

↓ 97/23/EC

Article 47

Addressees of the Directive

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

ANNEX I

ESSENTIAL SAFETY REQUIREMENTS

PRELIMINARY OBSERVATIONS

1. The obligations arising from the essential ☒ safety ☒ requirements listed in this Annex for pressure equipment also apply to assemblies where the corresponding ~~hazard~~ ☒ risk ☒ exists.
2. The essential ☒ safety ☒ requirements laid down in ~~the~~ ☒ this ☒ Directive are compulsory. The obligations ~~laid down~~ ☒ following from ☒ ~~in these~~ ☒ those ☒ essential ☒ safety ☒ requirements apply only if the corresponding ~~hazard~~ ☒ risk ☒ exists for the pressure equipment in question when it is used under conditions which are reasonably foreseeable by the manufacturer.
3. The manufacturer is under an obligation to analyse the ~~hazards~~ ☒ risks ☒ in order to identify those which apply to his equipment on account of pressure; he ~~must~~ ☒ shall ☒ then design and construct it taking account of his analysis.
4. The essential ☒ safety ☒ requirements are to be interpreted and applied in such a way as to take account of the state of the art and current practice at the time of design and manufacture as well as of technical and economic considerations which are consistent with a high degree of health and safety protection.

1. GENERAL

1.1. Pressure equipment ~~must~~ ☒ shall ☒ be designed, manufactured and checked, and if applicable equipped and installed, in such a way as to ensure its safety when put into service in accordance with the manufacturer's instructions, or in reasonably foreseeable conditions.

1.2. In choosing the most appropriate solutions, the manufacturer ~~must~~ ☒ shall ☒ apply the principles set out below in the following order:

- eliminate or reduce ~~hazards~~ ☒ risks ☒ as far as is reasonably practicable₂;
- apply appropriate protection measures against ~~hazards~~ ☒ risks ☒ which cannot be eliminated₂;
- where appropriate, inform users of residual ~~hazards~~ ☒ risks ☒ and indicate whether it is necessary to take appropriate special measures to reduce the risks at the time of installation and/or use.

1.3. Where the potential for misuse is known or can be clearly foreseen, the pressure equipment ~~must~~ ☒ shall ☒ be designed to prevent danger from such misuse or, if that is not

possible, adequate warning given that the pressure equipment ~~must~~ ☒ shall ☒ not be used in that way.

2. DESIGN

2.1. General

The pressure equipment ~~must~~ ☒ shall ☒ be properly designed taking all relevant factors into account in order to ensure that the equipment will be safe throughout its intended life.

The design ~~must~~ ☒ shall ☒ incorporate appropriate safety coefficients using comprehensive methods which are known to incorporate adequate safety margins against all relevant failure modes in a consistent manner.

2.2. Design for adequate strength

2.2.1. The pressure equipment ~~must~~ ☒ shall ☒ be designed for loadings appropriate to its intended use and other reasonably foreseeable operating conditions. In particular, the following factors ~~must~~ ☒ shall ☒ be taken into account:

↓ 97/23/EC

- internal/external pressure_{2.2};
- ambient and operational temperatures_{2.2};
- static pressure and mass of contents in operating and test conditions_{2.2};
- traffic, wind, earthquake loading_{2.2};
- reaction forces and moments which result from the supports, attachments, piping, etc._{2.2};
- corrosion and erosion, fatigue, etc._{2.2};
- decomposition of unstable fluids.

↓ 97/23/EC (adapted)

Various loadings which can occur at the same time ~~must~~ ☒ shall ☒ be considered, taking into account the probability of their simultaneous occurrence.

2.2.2. Design for adequate strength ~~must~~ ☒ shall ☒ be based on ☒ either of the following ☒:

- as a general rule, a calculation method, as described in 2.2.3, and supplemented if necessary by an experimental design method as described in 2.2.4_{2.2} ~~or~~

↓ 97/23/EC

- an experimental design method without calculation, as described in 2.2.4, when the product of the maximum allowable pressure PS and the volume V is less than 6000 bar·L or the product PS·DN less than 3000 bar.

2.2.3. Calculation method

(a) Pressure containment and other loading aspects

↓ 97/23/EC (adapted)

The allowable stresses for pressure equipment ~~must~~ ☒ shall ☒ be limited having regard to reasonably foreseeable failure modes under operating conditions. To this end, safety factors ~~must~~ ☒ shall ☒ be applied to eliminate fully any uncertainty arising out of manufacture, actual operational conditions, stresses, calculation models and the properties and behaviour of the material.

These calculation methods ~~must~~ ☒ shall ☒ provide sufficient safety margins consistent, where applicable, with the requirements of section point 7.

↓ 97/23/EC

The requirements set out above may be met by applying one of the following methods, as appropriate, if necessary as a supplement to or in combination with another method:

- design by formula_{2.2};
- design by analysis_{2.2};
- design by fracture mechanics_{2.2}.

(b) Resistance

↓ 97/23/EC (adapted)

Appropriate design calculations ~~must~~ ☒ shall ☒ be used to establish the resistance of the pressure equipment concerned.

In particular:

- the calculation pressures ~~must~~ ☒ shall ☒ not be less than the maximum allowable pressures and take into account static head and dynamic fluid pressures and the decomposition of unstable fluids. Where a vessel is separated into individual pressure-containing chambers, the partition wall ~~must~~ ☒ shall ☒ be designed on the basis of the highest possible chamber pressure relative to the lowest pressure possible in the adjoining chamber,
- the calculation temperatures ~~must~~ ☒ shall ☒ allow for appropriate safety margins,

- the design ~~must~~ ☒ shall ☒ take appropriate account of all possible combinations of temperature and pressure which might arise under reasonably foreseeable operating conditions for the equipment,
- the maximum stresses and peak stress concentrations ~~must~~ ☒ shall ☒ be kept within safe limits,
- the calculation for pressure containment ~~must~~ ☒ shall ☒ utilize the values appropriate to the properties of the material, based on documented data, having regard to the provisions set out in section point 4 together with appropriate safety factors. Material characteristics to be considered, where applicable, include:

↓ 97/23/EC

- yield strength, 0,2 % or 1,0 % proof strength as appropriate at calculation temperature_{3.2};
- tensile strength_{3.2};
- time-dependent strength, i.e. creep strength_{3.2};
- fatigue data_{3.2};
- Young's modulus (modulus of elasticity)_{3.2};
- appropriate amount of plastic strain_{3.2};

↓ 97/23/EC (adapted)

- ~~impact strength~~ ☒ bending rupture energy ☒_{3.2}

↓ 97/23/EC

- fracture toughness_{3.2}

↓ 97/23/EC (adapted)

- appropriate joint factors ~~must~~ ☒ shall ☒ be applied to the material properties depending, for example, on the type of non-destructive testing, the materials joined and the operating conditions envisaged_{3.2};
- the design ~~must~~ ☒ shall ☒ take appropriate account of all reasonably foreseeable degradation mechanisms (e.g. corrosion, creep, fatigue) commensurate with the intended use of the equipment. Attention ~~must~~ ☒ shall ☒ be drawn, in the instructions referred to in section point 3.4, to particular features of the design which are relevant to the life of the equipment, for example:

↓ 97/23/EC

- for creep: design hours of operation at specified temperatures_{3.2};

- for fatigue: design number of cycles at specified stress levels_{3.2};
- for corrosion: design corrosion allowance_{3.2}.

(c) Stability aspects

↓ 97/23/EC (adapted)

Where the calculated thickness does not allow for adequate structural stability, the necessary measures ~~must~~ ☒ shall ☒ be taken to remedy the situation taking into account the risks from transport and handling.

↓ 97/23/EC

2.2.4. Experimental design method

The design of the equipment may be validated, in all or in part, by an appropriate test programme carried out on a sample representative of the equipment or the category of equipment.

↓ 97/23/EC (adapted)

The test programme ~~must~~ ☒ shall ☒ be clearly defined prior to testing and accepted by the notified body responsible for the design conformity assessment module, where it exists.

This programme ~~must~~ ☒ shall ☒ define test conditions and criteria for acceptance or refusal. The actual values of the essential dimensions and characteristics of the materials which constitute the equipment tested shall be measured before the test.

Where appropriate, during tests, it ~~must~~ ☒ shall ☒ be possible to observe the critical zones of the pressure equipment with adequate instrumentation capable of registering strains and stresses with sufficient precision.

The test programme ~~must~~ ☒ shall ☒ include:

↓ 97/23/EC

(a) A pressure strength test, the purpose of which is to check that, at a pressure with a defined safety margin in relation to the maximum allowable pressure, the equipment does not exhibit significant leaks or deformation exceeding a determined threshold.

↓ 97/23/EC (adapted)

The test pressure ~~must~~ ☒ shall ☒ be determined on the basis of the differences between the values of the geometrical and material characteristics measures under test conditions and the values used for design purposes; it ~~must~~ ☒ shall ☒ take into account the differences between the test and design temperatures;

- (b) where the risk of creep or fatigue exists, appropriate tests determined on the basis of the service conditions laid down for the equipment, for instance hold time at specified temperatures, number of cycles at specified stress-levels₂ ~~etc.~~;
- (c) where necessary, additional tests concerning other factors referred to in 2.2.1 such as corrosion, external damage₂ ~~etc.~~.

2.3. Provisions to ensure safe handling and operation

The method of operation specified for pressure equipment ~~must~~ ☒ shall ☒ be such as to preclude any reasonably foreseeable risk in operation of the equipment. Particular attention ~~must~~ ☒ shall ☒ be paid, where appropriate, to:

↓ 97/23/EC

- closures and openings₂;
- dangerous discharge of pressure relief blow-off₂;
- devices to prevent physical access whilst pressure or a vacuum exists₂;
- surface temperature taking into consideration the intended use₂;
- decomposition of unstable fluids.

↓ 97/23/EC (adapted)

In particular, pressure equipment fitted with an access door ~~must~~ ☒ shall ☒ be equipped with an automatic or manual device enabling the user easily to ascertain that the opening will not present any hazard ☒ risk ☒. Furthermore, where the opening can be operated quickly, the pressure equipment ~~must~~ ☒ shall ☒ be fitted with a device to prevent it being opened whenever the pressure or temperature of the fluid presents a hazard ☒ risk ☒.

2.4. Means of examination

- (a) Pressure equipment ~~must~~ ☒ shall ☒ be designed and constructed so that all necessary examinations to ensure safety can be carried out;
- (b) Means of determining the internal condition of the equipment ~~must~~ ☒ shall ☒ be available, where it is necessary to ensure the continued safety of the equipment, such as access openings allowing physical access to the inside of the pressure equipment so that appropriate examinations can be carried out safely and ergonomically;
- (c) Other means of ensuring the safe condition of the pressure equipment may be applied ☒ in any of the following situations ☒.
- where it is too small for physical internal access₂ ~~or~~;
 - where opening the pressure equipment would adversely affect the inside₂ ~~or~~;

↓ 97/23/EC

- where the substance contained has been shown not to be harmful to the material from which the pressure equipment is made and no other internal degradation mechanisms are reasonably foreseeable.

2.5. Means of draining and venting

↓ 97/23/EC (adapted)

Adequate means ~~must~~ ☒ shall ☒ be provided for the draining and venting of pressure equipment where necessary:

- to avoid harmful effects such as water hammer, vacuum collapse, corrosion and uncontrolled chemical reactions. All stages of operation and testing, particularly pressure testing, ~~must~~ ☒ shall ☒ be considered;

↓ 97/23/EC

- to permit cleaning, inspection and maintenance in a safe manner.

2.6. Corrosion or other chemical attack

↓ 97/23/EC (adapted)

Where necessary, adequate allowance or protection against corrosion or other chemical attack ~~must~~ ☒ shall ☒ be provided, taking due account of the intended and reasonably foreseeable use.

2.7. Wear

Where severe conditions of erosion or abrasion may arise, adequate measures ~~must~~ ☒ shall ☒ be taken to:

↓ 97/23/EC

- minimize that effect by appropriate design, e.g. additional material thickness, or by the use of liners or cladding materials;
- permit replacement of parts which are most affected;
- draw attention, in the instructions referred to in point 3.4, to measures necessary for continued safe use.

2.8. Assemblies

↓ 97/23/EC (adapted)

Assemblies ~~must~~ ☒ shall ☒ be so designed that:

↓ 97/23/EC

- the components to be assembled together are suitable and reliable for their duty;
- all the components are properly integrated and assembled in an appropriate manner.

2.9. Provisions for filling and discharge

↓ 97/23/EC (adapted)

Where appropriate, the pressure equipment ~~must~~ ☒ shall ☒ be so designed and provided with accessories, or provision made for their fitting, as to ensure safe filling and discharge in particular with respect to ~~hazards~~ ☒ risks ☒ such as:

↓ 97/23/EC

- (a) on filling:
 - overfilling or overpressurization having regard in particular to the filling ratio and to vapour pressure at the reference temperature;
 - instability of the pressure equipment;
- (b) on discharge: the uncontrolled release of the pressurized fluid;
- (c) on filling or discharge: unsafe connection and disconnection.

2.10. Protection against exceeding the allowable limits of pressure equipment

↓ 97/23/EC (adapted)

Where, under reasonably foreseeable conditions, the allowable limits could be exceeded, the pressure equipment ~~must~~ ☒ shall ☒ be fitted with, or provision made for the fitting of, suitable protective devices, unless the equipment is intended to be protected by other protective devices within an assembly.

The suitable device or combination of such devices ~~must~~ ☒ shall ☒ be determined on the basis of the particular characteristics of the equipment or assembly.

↓ 97/23/EC

Suitable protective devices and combinations thereof comprise:

- (a) safety accessories as defined in Article ~~12(4)~~, ~~section 2.1.3~~;
- (b) where appropriate, adequate monitoring devices such as indicators and/or alarms which enable adequate action to be taken either automatically or manually to keep the pressure equipment within the allowable limits.

2.11. Safety accessories

↓ 97/23/EC (adapted)

2.11.1. Safety accessories ~~must~~ ☒ shall ☒:

↓ 97/23/EC

- be so designed and constructed as to be reliable and suitable for their intended duty and take into account the maintenance and testing requirements of the devices, where applicable_{2.2};
- be independent of other functions, unless their safety function cannot be affected by such other functions_{2.2};
- comply with appropriate design principles in order to obtain suitable and reliable protection. These principles include, in particular, fail-safe modes, redundancy, diversity and self-diagnosis.

2.11.2. Pressure limiting devices

↓ 97/23/EC (adapted)

These devices ~~must~~ ☒ shall ☒ be so designed that the pressure will not permanently exceed the maximum allowable pressure PS; however a short duration pressure surge in keeping with the specifications laid down in 7.3 is allowable, where appropriate.

2.11.3. Temperature monitoring devices

These devices ~~must~~ ☒ shall ☒ have an adequate response time on safety grounds, consistent with the measurement function.

2.12. External fire

Where necessary, pressure equipment ~~must~~ ☒ shall ☒ be so designed and, where appropriate, fitted with suitable accessories, or provision made for their fitting, to meet damage-limitation requirements in the event of external fire, having particular regard to its intended use.

3. MANUFACTURING

3.1. Manufacturing procedures

The manufacturer ~~must~~ ☒ shall ☒ ensure the competent execution of the provisions set out at the design stage by applying the appropriate techniques and relevant procedures, especially with a view to the aspects set out below.

3.1.1. Preparation of the component parts

Preparation of the component parts (e.g. forming and chamfering) ~~must~~ ☒ shall ☒ not give rise to defects or cracks or changes in the mechanical characteristics likely to be detrimental to the safety of the pressure equipment.

3.1.2. Permanent joining

Permanent joints and adjacent zones ~~must~~ ☒ shall ☒ be free of any surface or internal defects detrimental to the safety of the equipment.

The properties of permanent joints ~~must~~ ☒ shall ☒ meet the minimum properties specified for the materials to be joined unless other relevant property values are specifically taken into account in the design calculations.

For pressure equipment, permanent joining of components which contribute to the pressure resistance of equipment and components which are directly attached to them ~~must~~ ☒ shall ☒ be carried out by suitably qualified personnel according to suitable operating procedures.

For pressure equipment in categories II, III and IV, operating procedures and personnel ~~must~~ ☒ shall ☒ be approved by a competent third party which, at the manufacturer's discretion, may be:

↓ 97/23/EC

- a notified body²²;
 - a third-party organization recognized by a Member State as provided for in Article ~~13~~20.
-

↓ 97/23/EC (adapted)
⇒ new

To carry out these approvals the third party must perform examinations and tests as set out in the appropriate harmonised standards or equivalent examinations and tests or ~~must~~ ☒ shall ☒ have them performed.

3.1.3. Non-destructive tests

For pressure equipment, non-destructive tests of permanent joints ~~must~~ ☒ shall ☒ be carried out by suitable qualified personnel. For pressure equipment in categories III and IV, the personnel ~~must~~ ☒ shall ☒ be approved by a third-party organization recognized by a Member State pursuant to Article ~~13~~20.

3.1.4. Heat treatment

Where there is a risk that the manufacturing process will change the material properties to an extent which would impair the safety of the pressure equipment, suitable heat treatment ~~must~~ ☒ shall ☒ be applied at the appropriate stage of manufacture.

3.1.5. Traceability

Suitable procedures ~~must~~ ☒ shall ☒ be established and maintained for identifying the material making up the components of the equipment which contribute to pressure resistance by suitable means from receipt, through production, up to the final test of the manufactured pressure equipment.

3.2. Final assessment

Pressure equipment ~~must~~ ☒ shall ☒ be subjected to final assessment as described below.

3.2.1. Final inspection

Pressure equipment ~~must~~ ☒ shall ☒ undergo a final inspection to assess visually and by examination of the accompanying documents compliance with the requirements of the Directive. Test carried out during manufacture may be taken into account. As far as is necessary on safety grounds, the final inspection ~~must~~ ☒ shall ☒ be carried out internally and externally on every part of the equipment, where appropriate in the course of manufacture (e.g. where examination during the final inspection is no longer possible).

3.2.2. Proof test

Final assessment of pressure equipment ~~must~~ ☒ shall ☒ include a test for the pressure containment aspect, which will normally take the form of a hydrostatic pressure test at a pressure at least equal, where appropriate, to the value laid down in 7.4.

For category I series-produced pressure equipment, this test may be performed on a statistical basis.

Where the hydrostatic pressure test is harmful or impractical, other tests of a recognized value may be carried out. For tests other than the hydrostatic pressure test, additional measures, such as non-destructive tests or other methods of equivalent validity, ~~must~~ ☒ shall ☒ be applied before those tests are carried out.

3.2.3. Inspection of safety devices

For assemblies, the final assessment ~~must~~ ☒ shall ☒ also include a check of the safety devices intended to check full compliance with the requirements referred to in 2.10.

3.3. Marking and labelling

In addition to the CE marking referred to in Articles ~~15~~ 18 and 19, the following information ~~must~~ ☒ shall ☒ be provided:

(a) for all pressure equipment:

- the name and address or other means of identification of the manufacturer and, where appropriate, of ~~his authorized representative established within the Community~~ ⇒ the importer ⇐ ~~2.2~~

↓ 97/23/EC

- the year of manufacture; ~~2.2~~
- identification of the pressure equipment according to its nature, such as type, series or batch identification and serial number; ~~2.2~~
- essential maximum/minimum allowable limits; ~~2.2~~

(b) depending on the type of pressure equipment, further information necessary for safe installation, operation or use and, where applicable, maintenance and periodic inspection such as:

- the volume V of the pressure equipment in $L_{\bar{2.2}}$;
- the nominal size for piping $DN_{\bar{2.2}}$;
- the test pressure PT applied in bar and date $_{\bar{2.2}}$;
- safety device set pressure in bar $_{\bar{2.2}}$;
- output of the pressure equipment in $kW_{\bar{2.2}}$;
- supply voltage in V (volts) $_{\bar{2.2}}$;
- intended use $_{\bar{2.2}}$;
- filling ratio $kg/L_{\bar{2.2}}$;
- maximum filling mass in $kg_{\bar{2.2}}$;
- tare mass in $kg_{\bar{2.2}}$;

↓ 97/23/EC
⇒ new

- the ~~product~~ ⇒ fluid ⇐ group $_{\bar{2.2}}$

↓ 97/23/EC

(c) where necessary, warnings fixed to the pressure equipment drawing attention to misuse which experience has shown might occur.

↓ 97/23/EC (adapted)

The CE marking and the required information ~~must~~ ☒ shall ☒ be given on the pressure equipment or on a dataplate firmly attached to it, with the following exceptions:

↓ 97/23/EC

- where applicable, appropriate documentation may be used to avoid repetitive marking of individual parts such as piping components, intended for the same assembly. This applies to CE marking and other marking and labelling referred to in this Annex;
- where the pressure equipment is too small, e.g. accessories, the information referred to in point (b) may be given on a label attached to that pressure equipment;

- labelling or other adequate means may be used for the mass to be filled and the warnings referred to in point (c), provided it remains legible for the appropriate period of time.

3.4. Operating instructions

↓ 97/23/EC (adapted)

⇒ new

- (a) When pressure equipment is ~~placed~~ ⇒ made available ⇐ on the market, it ~~must~~ ☒ shall ☒ be accompanied, as far as relevant, with instructions for the user, containing all the necessary safety information relating to:

↓ 97/23/EC

- mounting including assembling of different pieces of pressure equipment_{2.2};
- putting into service_{2.2};
- use_{2.2};
- maintenance including checks by the user_{2.2}.

↓ 97/23/EC (adapted)

- (b) Instructions ~~must~~ ☒ shall ☒ cover information affixed to the pressure equipment in accordance with 3.3, with the exception of serial identification, and ~~must~~ ☒ shall ☒ be accompanied, where appropriate, by the technical documents, drawings and ~~diagrams~~ ☒ schemes ☒ necessary for a full understanding of these instructions;

- (c) If appropriate, these instructions ~~must~~ ☒ shall ☒ also refer to ~~hazards~~ ☒ risks ☒ arising from misuse in accordance with 1.3 and particular features of the design in accordance with 2.2.3.

4. MATERIALS

Materials used for the manufacture of pressure equipment ~~must~~ ☒ shall ☒ be suitable for such application during the scheduled lifetime unless replacement is foreseen.

↓ 97/23/EC

Welding consumables and other joining materials need fulfil only the relevant requirements of 4.1, 4.2 (a) and the first paragraph of 4.3, in an appropriate way, both individually and in a joined structure.

↓ 97/23/EC (adapted)

- 4.1. Materials for pressurised parts ~~must~~ ☒ shall ☒:

- (a) have appropriate properties for all operating conditions which are reasonably foreseeable and for all test conditions, and in particular they should be sufficiently ductile and

tough. Where appropriate, the characteristics of the materials ~~must~~ ☒ shall ☒ comply with the requirements of 7.5. Moreover, due care should be exercised in particular in selecting materials in order to prevent brittle-type fracture where necessary; where for specific reasons brittle material has to be used appropriate measures ~~must~~ ☒ shall ☒ be taken;

(b) be sufficiently chemically resistant to the fluid contained in the pressure equipment; the chemical and physical properties necessary for operational safety ~~must~~ ☒ shall ☒ not be significantly affected within the scheduled lifetime of the equipment;

↓ 97/23/EC

(c) not be significantly affected by ageing;

(d) be suitable for the intended processing procedures;

(e) be selected in order to avoid significant undesirable effects when the various materials are put together.

↓ 97/23/EC (adapted)

4.2. ☒ The pressure equipment manufacturer shall ☒:

(a) ~~The pressure equipment manufacturer must~~ define in an appropriate manner the values necessary for the design calculations referred to in 2.2.3 and the essential characteristics of the materials and their treatment referred to in 4.1;

(b) ~~the manufacturer must~~ provide in his technical documentation elements relating to compliance with the materials specifications of the Directive in one of the following forms:

↓ 97/23/EC

- by using materials which comply with harmonised standards₅;
- by using materials covered by a European approval of pressure equipment materials in accordance with Article ~~11~~15₅;
- by a particular material appraisal₅.

↓ 97/23/EC (adapted)

(c) for pressure equipment in categories III and IV, ☒ a specific assessment of the ☒ particular ☒ material ☒ appraisal ~~as referred to in the third indent of (b)~~ ~~must~~ ☒ shall ☒ be performed by the notified body in charge of conformity assessment procedures for the pressure equipment.

4.3. The equipment manufacturer ~~must~~ ☒ shall ☒ take appropriate measures to ensure that the material used conforms with the required specification. In particular, documentation prepared by the material manufacturer affirming compliance with a specification ~~must~~ ☒ shall ☒ be obtained for all materials.

For the main pressure-bearing parts of equipment in categories II, III and IV, this ~~must~~ ☒ shall ☒ take the form of a certificate of specific product control.

Where a material manufacturer has an appropriate quality-assurance system, certified by a competent body established within the ~~Community~~ ☒ Union ☒ and having undergone a specific assessment for materials, certificates issued by the manufacturer are presumed to certify conformity with the relevant requirements of this ~~section~~ point.

↓ 97/23/EC

SPECIFIC PRESSURE EQUIPMENT REQUIREMENTS

In addition to the applicable requirements of ~~sections~~ points 1 to 4, the following requirements apply to the pressure equipment covered by ~~sections~~ points 5 and 6.

5. FIRED OR OTHERWISE HEATED PRESSURE EQUIPMENT WITH A RISK OF OVERHEATING AS REFERRED TO IN ARTICLE ~~34~~ (1)

This pressure equipment includes:

↓ 97/23/EC (adapted)

- steam and hot-water generators as referred to in Article ~~34(b)~~, ~~section 1.2~~, such as fired steam and hot-water boilers, superheaters and reheaters, waste-heat boilers, waste incineration boilers, electrode or immersion-type electrically heated boilers, pressure cookers, together with their accessories and where applicable their systems for treatment of feedwater and for fuel supply; ~~and~~
- process-heating equipment for other than steam and hot water generation falling under Article ~~34(a)~~, ~~section 1.1~~, such as heaters for chemical and other similar processes and pressurized food-processing equipment.

This pressure equipment ~~must~~ ☒ shall ☒ be calculated, designed and constructed so as to avoid ~~to~~ ☒ or ☒ minimize risks of a significant loss of containment from overheating. In particular it ~~must~~ ☒ shall ☒ be ensured, where applicable, that:

↓ 97/23/EC

- (a) appropriate means of protection are provided to restrict operating parameters such as heat input, heat take-off and, where applicable, fluid level so as to avoid any risk of local and general overheating;
- (b) sampling points are provided where required to allow evaluation of the properties of the fluid so as to avoid risks related to deposits and/or corrosion;
- (c) adequate provisions are made to eliminate risks of damage from deposits;
- (d) means of safe removal of residual heat after shutdown are provided;

(e) steps are taken to avoid a dangerous accumulation of ignitable mixtures of combustible substances and air, or flame blowback.

↓ 97/23/EC (adapted)

6. PIPING AS REFERRED TO IN ARTICLE ~~34 (c)~~, ~~SECTION 1.3~~

Design and construction ~~must~~ ☒ shall ☒ ensure:

↓ 97/23/EC

(a) that the risk of overstressing from inadmissible free movement or excessive forces being produced, e.g. on flanges, connections, bellows or hoses, is adequately controlled by means such as support, constraint, anchoring, alignment and pre-tension;

(b) that where there is a possibility of condensation occurring inside pipes for gaseous fluids, means are provided for drainage and removal of deposits from low areas to avoid damage from water hammer or corrosion;

(c) that due consideration is given to the potential damage from turbulence and formation of vortices; the relevant parts of 2.7 are applicable;

(d) that due consideration is given to the risk of fatigue due to vibrations in pipes;

(e) that, where fluids of Group 1 are contained in the piping, appropriate means are provided to isolate «take-off» pipes the size of which represents a significant risk;

↓ 97/23/EC (adapted)

(f) that the risk of inadvertent discharge is minimized; the take-off points ~~must~~ ☒ shall ☒ be clearly marked on the permanent side, indicating the fluid contained;

↓ 97/23/EC

(g) that the position and route of underground piping is at least recorded in the technical documentation to facilitate safe maintenance, inspection or repair.

7. SPECIFIC QUANTITATIVE REQUIREMENTS FOR CERTAIN PRESSURE EQUIPMENT

↓ 97/23/EC (adapted)

The following provisions apply as a general rule. However, where they are not applied, including in cases where materials are not specifically referred to and no harmonised standards are applied, the manufacturer ~~must~~ ☒ shall ☒ demonstrate that appropriate measures have been taken to achieve an equivalent overall level of safety.

~~This section is an integral part of Annex I.~~ The provisions laid down in this section supplement the essential ☒ safety ☒ requirements of ~~sections~~ points 1 to 6 for the pressure equipment to which they apply.

7.1.1. Symbols

$R_{c/t}$, yield limit, indicates the value at the calculation temperature of:

- the upper flow limit for a material presenting upper and lower flow limits $\underline{\sigma}_L$;
- the 1,0 % proof strength of austenitic steel and non-alloyed aluminium $\underline{\sigma}_L$;
- the 0,2 % proof strength in other cases.

$R_{m/20}$ indicates the minimum value of the ultimate tensile strength at 20 °C.

$R_{m/t}$ designates the ultimate \otimes tensile \otimes strength at the calculation temperature.

7.1.2. The permissible general membrane stress for predominantly static loads and for temperatures outside the range in which creep is significant ~~must~~ ☒ shall ☒ not exceed the smaller of the following values, according to the material used:

- in the case of ferritic steel including normalized (normalized rolled) steel and excluding fine-grained steel and specially heat-treated steel, $\frac{2}{3}$ of $R_{e/t}$ and $\frac{5}{12}$ of $R_{m/20}$;
- in the case of austenitic steel:
 - if its elongation after rupture exceeds 30 %, $\frac{2}{3}$ of $R_{e/t}$
 - or, alternatively, and if its elongation after rupture exceeds 35 %, $\frac{5}{6}$ of $R_{e/t}$ and $\frac{1}{3}$ of $R_{m/t}$;
- in the case of non-alloy or low-alloy cast steel, $\frac{10}{19}$ of $R_{e/t}$ and $\frac{1}{3}$ of $R_{m/20}$;
- in the case of aluminium, $\frac{2}{3}$ of $R_{e/t}$;
- in the case of aluminium alloys excluding precipitation hardening alloys $\frac{2}{3}$ of $R_{e/t}$ and $\frac{5}{12}$ of $R_{m/20}$.

7.2. Joint coefficients

For welded joints, the joint coefficient ~~must~~ ☐ shall ☐ not exceed the following values:

↓ 97/23/EC

- for equipment subject to destructive and non-destructive tests which confirm that the whole series of joints show no significant defects: 1,5;
 - for equipment subject to random non-destructive testing: 0,85;
 - for equipment not subject to non-destructive testing other than visual inspection: 0,7.
-

↓ 97/23/EC (adapted)

If necessary, the type of stress and the mechanical and technological properties of the joint ~~must~~ ☒ shall ☒ also be taken into account.

7.3. Pressure limiting devices, particularly for pressure vessels

The momentary pressure surge referred to in 2.11.2 ~~must~~ ☒ shall ☒ be kept to 10 % of the maximum allowable pressure.

7.4. Hydrostatic test pressure

For pressure vessels, the hydrostatic test pressure referred to in 3.2.2 ~~must~~ ☒ shall ☒ be no less than ☒ either of the following ☒.

- that corresponding to the maximum loading to which the pressure equipment may be subject in service taking into account its maximum allowable pressure and its maximum allowable temperature, multiplied by the coefficient 1,25; ~~or~~
- the maximum allowable pressure multiplied by the coefficient 1,43, whichever is the greater.

7.5. Material characteristics

Unless other values are required in accordance with other criteria that ~~must~~ ☒ shall ☒ be taken into account, a steel is considered as sufficiently ductile to satisfy 4.1 (a) if, in a tensile test carried out by a standard procedure, its elongation after rupture is no less than 14 % and its bending rupture energy measured on an ISO V test-piece is no less than 27 J, at a temperature not greater than 20 °C but not higher than the lowest scheduled operating temperature.

ANNEX II

CONFORMITY ASSESSMENT TABLES

1. The references in the tables to categories of modules are the following:

↓ 97/23/EC (adapted)

I	=	Module A
II	=	Module A ₁₂ , D1, E1
III	=	Modules B ₁ ⊗ (design type) ⊗ + D, B ₂ ⊗ (design type) ⊗ + F, B ₃ ⊗ (combination of production type and design type) ⊗ + E, B ₄ ⊗ (combination of production type and design type) ⊗ + C ₁₂ , H
IV	=	Modules B ⊗ (combination of production type and design type) ⊗ + D, B ⊗ (combination of production type and design type) ⊗ + F, G, H1

2. The safety accessories defined in Article ~~12(4), Section 2.1.3,~~ and referred to in Article ~~34(1)(d), Section 1.4,~~ are classified in category IV. However, by way of exception, safety accessories manufactured for specific equipment may be classified in the same category as the equipment they protect.

3. The pressure accessories defined in Article ~~12(5), Section 2.1.4,~~ and referred to in Article ~~34(1)(d), Section 1.4,~~ are classified on the basis of:

- their maximum allowable pressure $PS_{\underline{S}}$; ~~and~~
- their volume V or their nominal size DN, as appropriate; ~~and~~
- the group of fluids for which they are intended; ~~and~~

and ~~†~~The appropriate table for vessels or piping is to be used to determine the conformity assessment category.

Where both the volume and the nominal size are considered appropriate in the second indent **✖** of the first subparagraph **✖**, the pressure accessory ~~must~~ **✖** shall **✖** be classified in the highest category.

↓ 97/23/EC

4. The demarcation lines in the following conformity assessment tables indicate the upper limit for each category.

↓ 97/23/EC (adapted)

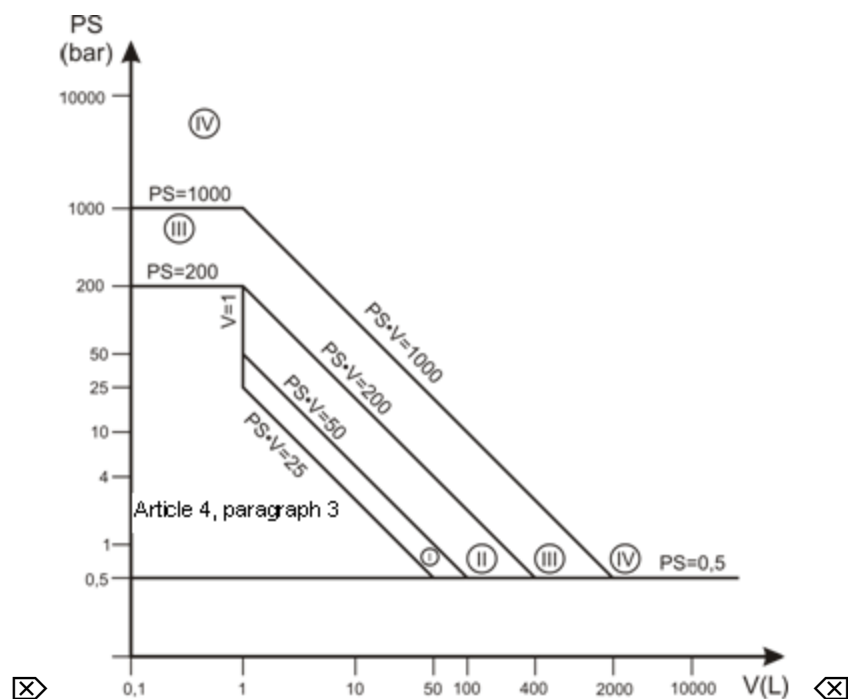


Table 1

Vessels referred to in Article 34, Section 1.1 (1)(a)(i), first indent

Exceptionally, vessels intended to contain an unstable gas and falling within categories I or II on the basis of table 1 ~~must~~ shall be classified in category III.

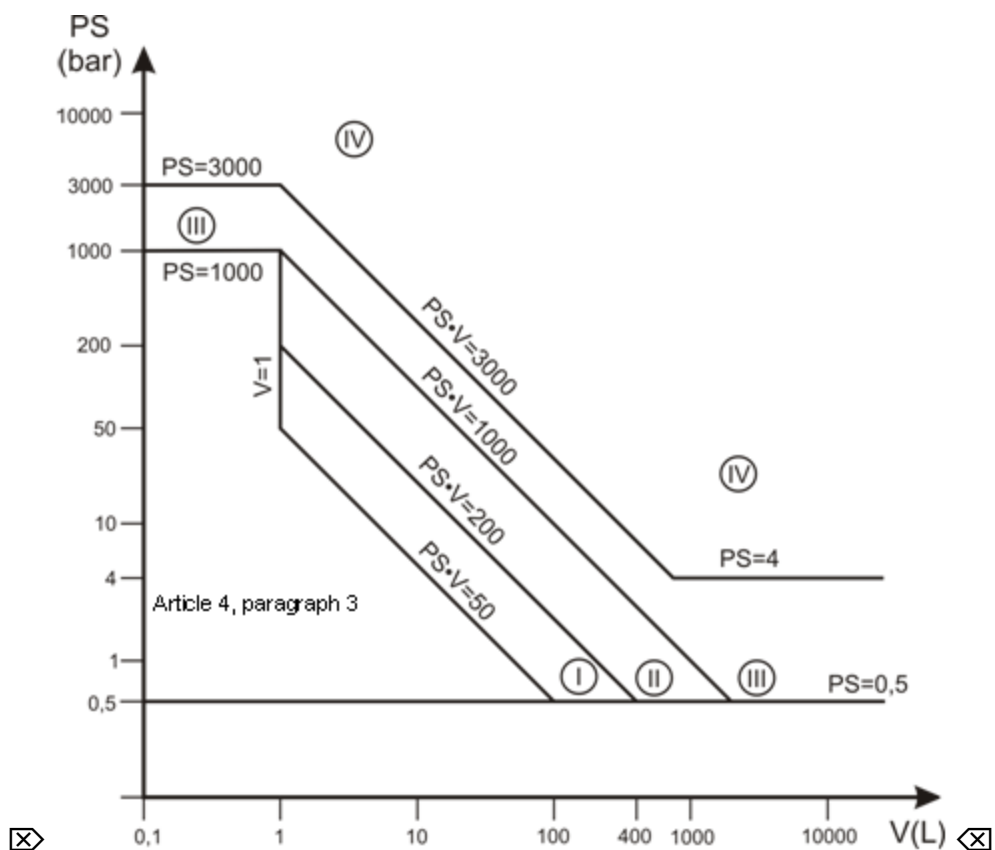


Table 2

Vessels referred to in Article ~~34, Section 1.1~~ (1)(a)(i), second indent

Exceptionally, portable extinguishers and bottles for breathing equipment ~~must~~ ☐ shall ☐ be classified at least in category III.

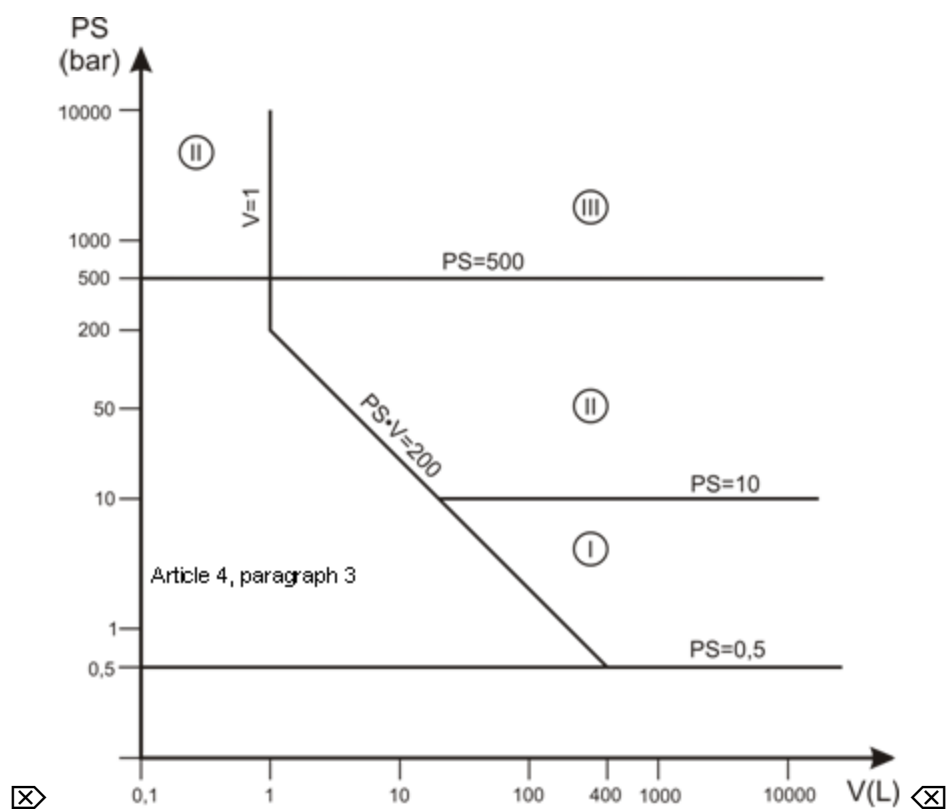


Table 3

Vessels referred to in Article ~~34, Section 1.1 (1)(ba)(ii)~~, first indent

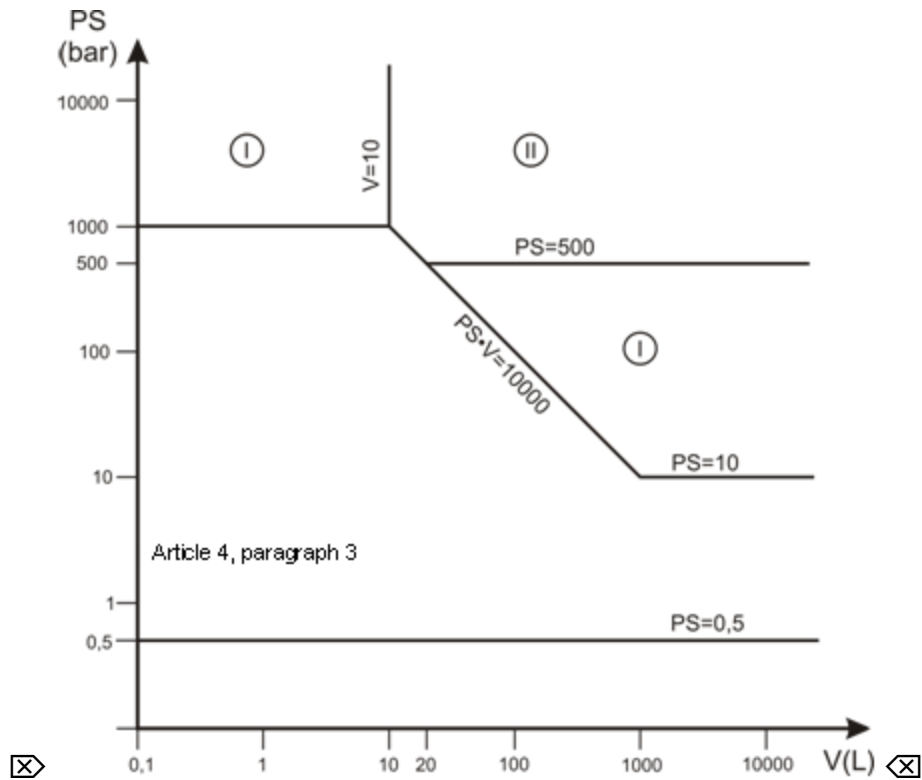


Table 4

Vessels referred to in Article ~~34(1)(a)(ii), Section 1.1 (b)~~, second indent

Exceptionally, assemblies intended for generating warm water as referred to in Article ~~34~~ (2)(c), ~~Section 2.3~~, must ~~shall~~ be subject either to an ~~EC design~~ EU-type examination (Module B~~1~~ - design type) with respect to their conformity with the essential requirements referred to in ~~Sections points~~ 2.10, 2.11, 3.4, 5 (a) and 5 (d) of Annex I, or to full quality assurance (Module H).

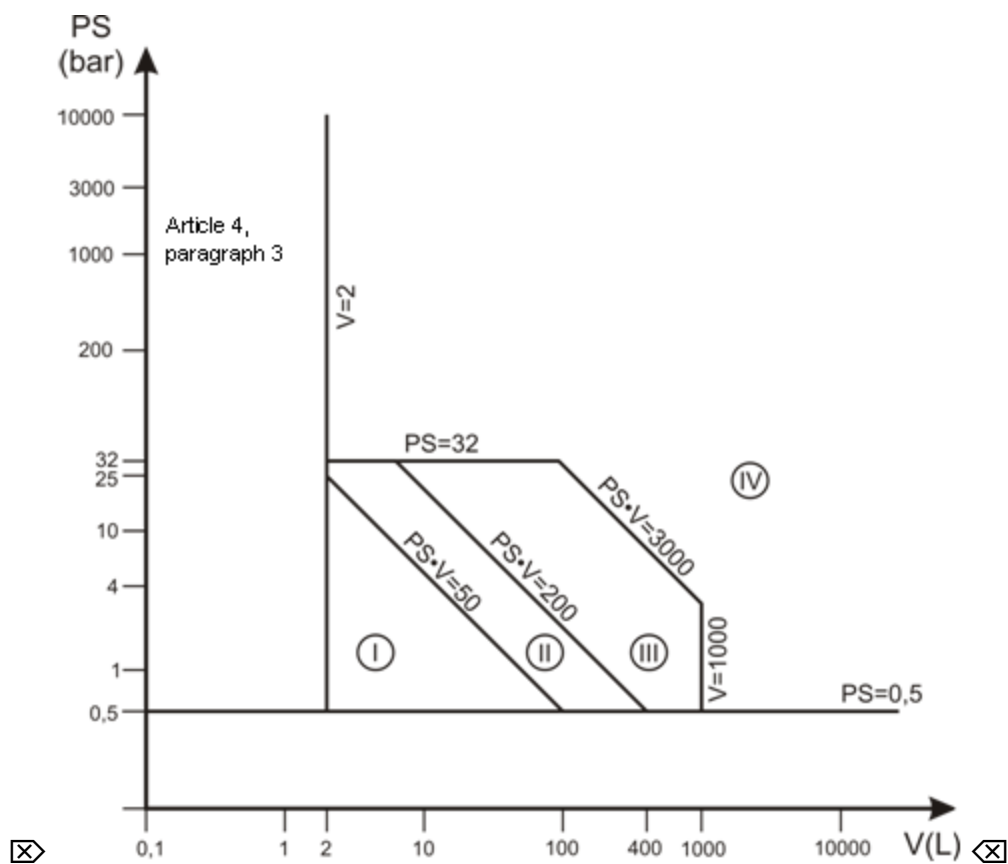


Table 5

Pressure equipment referred to in Article 34(1)(b), Section 1.2

Exceptionally, the design of pressure-cookers ~~must~~ ☒ shall ☒ be subject to a conformity assessment procedure equivalent to at least one of the category III modules.

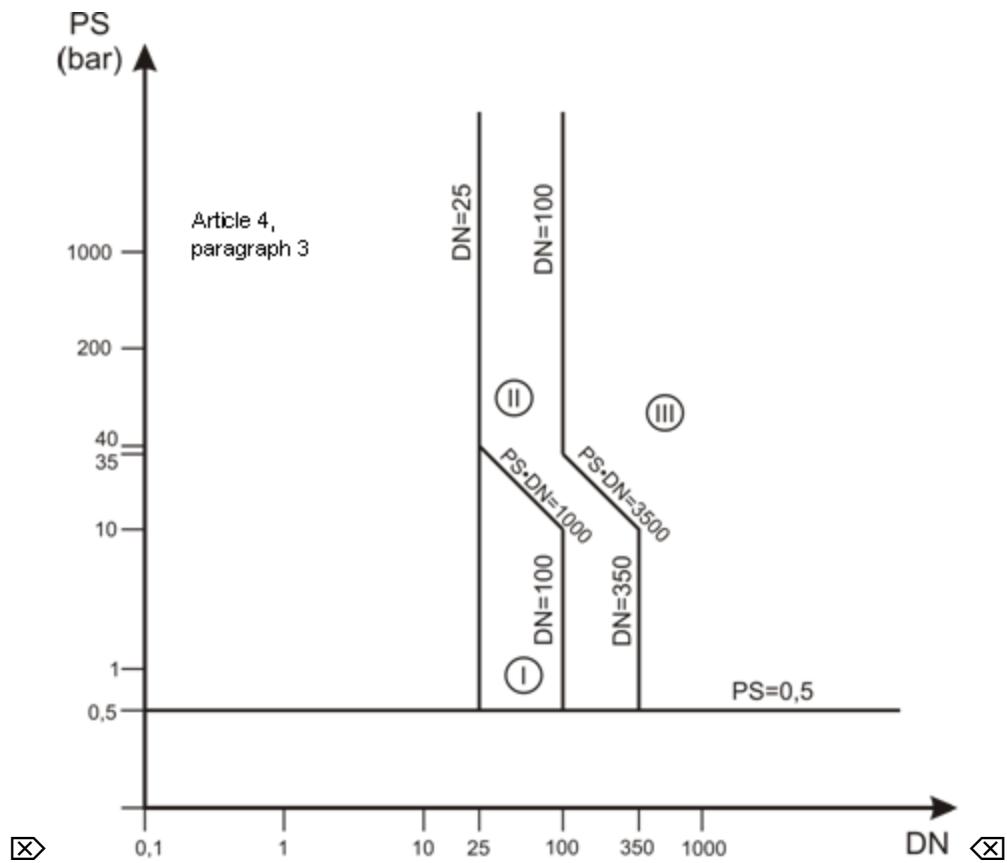


Table 6

Piping referred to in Article 34(1)(c)(i), Section 1.3 (a), first indent

Exceptionally, piping intended for unstable gases and falling within categories I or II on the basis of Table 6 ~~must~~ ☐ shall ☐ be classified in category III.

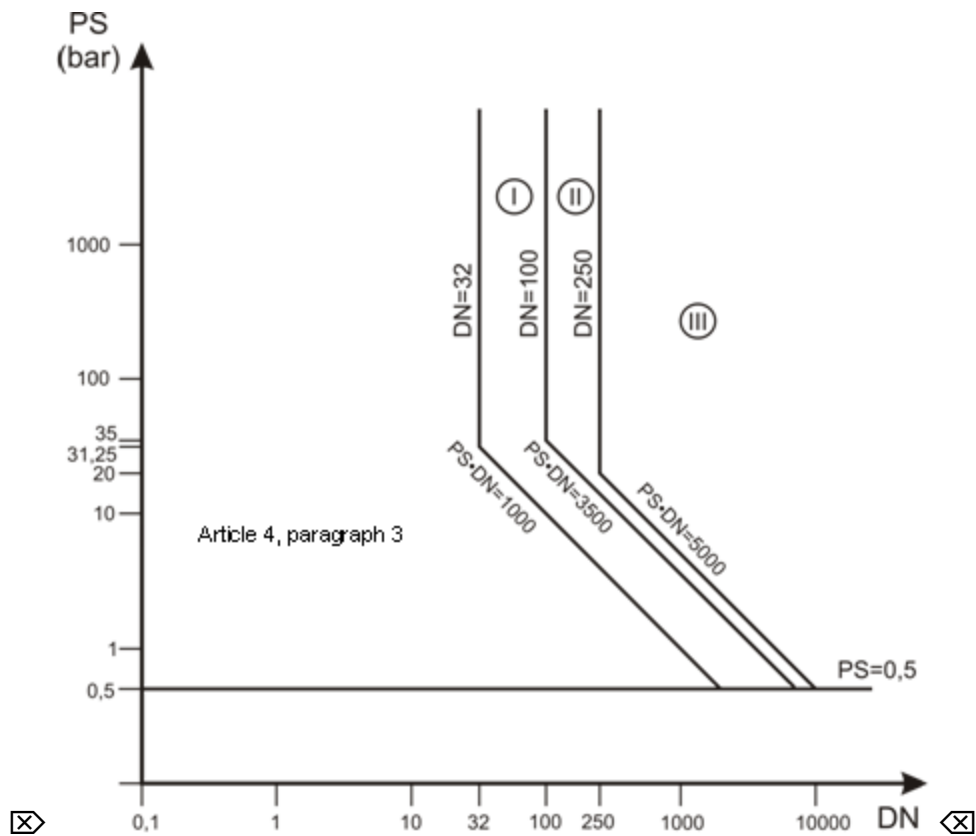


Table 7

Piping referred to in Article 34(1)(c)(i), Section 1.3 (a), second indent

Exceptionally, all piping containing fluids at a temperature greater than 350 °C and falling within category II on the basis of Table 7 ~~must~~ ☐ shall ☐ be classified in category III.

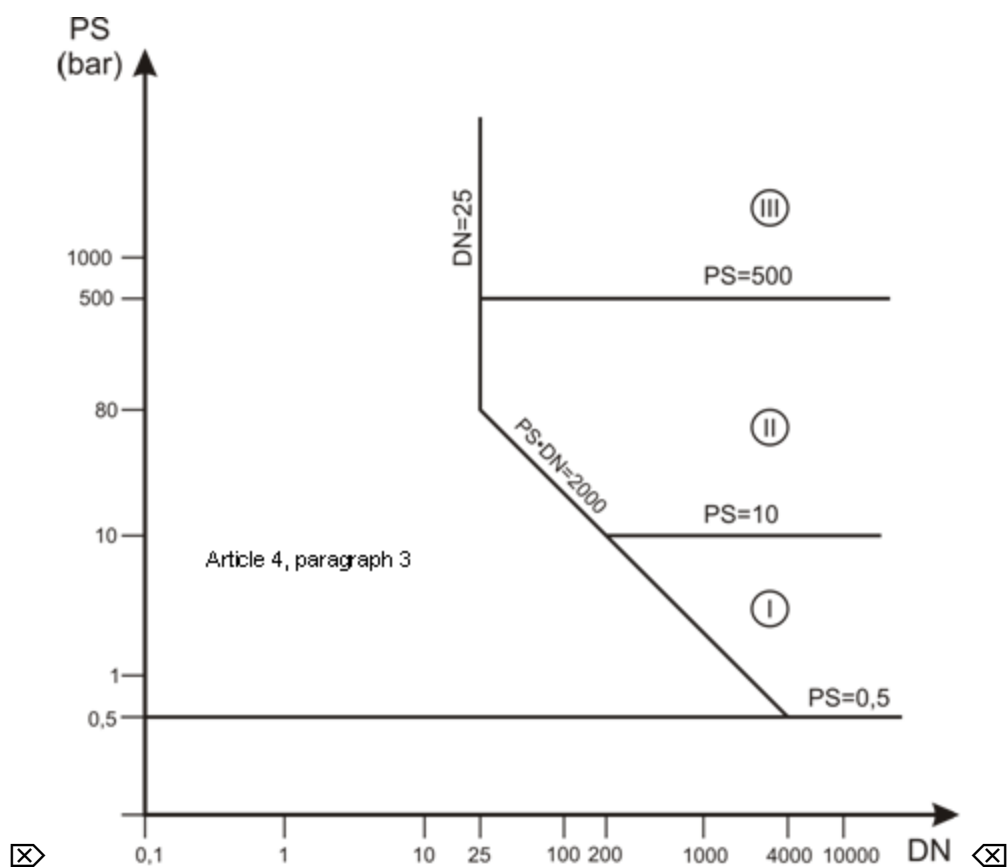


Table 8

Piping referred to in Article 34(1)(c)(ii), Section 1.3 (b), first indent

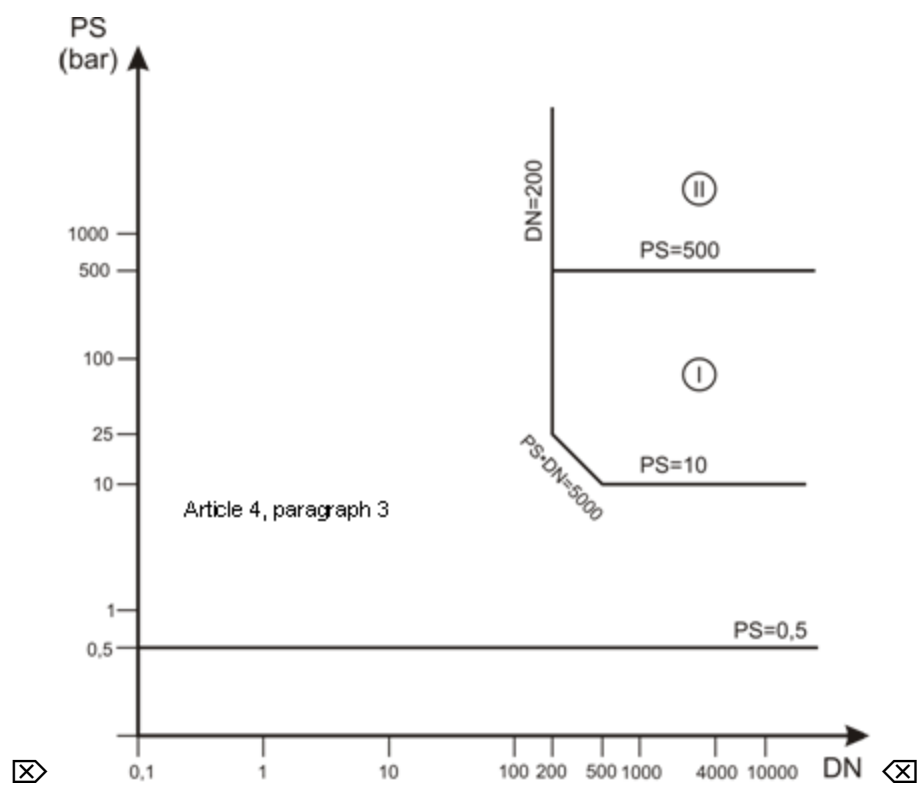


Table 9

Piping referred to in Article ~~34(1)(c)(ii), Section 1.3 (b)~~, second indent

ANNEX III

CONFORMITY ASSESSMENT PROCEDURES

The obligations arising from the provisions on pressure equipment in this Annex also apply to assemblies.

1. MODULE A: (INTERNAL PRODUCTION CONTROL)

~~1. This module describes the procedure whereby the manufacturer or his authorized representative established within the Community who carries out the obligations laid down in section 2 ensures and declares that pressure equipment satisfies the requirements of the Directive which apply to it.~~

~~The manufacturer, or his authorized representative established within the Community, must affix the CE marking to each item of pressure equipment and draw up a written declaration of conformity.~~

↓ new

1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that the pressure equipment concerned satisfy the requirements of this Directive.

↓ 97/23/EC (adapted)

2. ☒ Technical documentation ☒

~~The manufacturer must draw up ☒ shall establish ☒ the technical documentation, described in section 3 and either the manufacturer or his authorized representative established within the Community must keep it at the disposal of the relevant national authorities for inspection purposes for a period of ten years after the last of the pressure equipment has been manufactured.~~

↓ 97/23/EC

~~Where neither the manufacturer nor his authorized representative is established within the Community, the obligation to keep the technical documentation available is the responsibility of the person who places the pressure equipment on the Community market.~~

↓ 97/23/EC (adapted)

⇒ new

3. The technical documentation ~~must enable~~ ☒ shall make it possible to ☒ ~~an assessment to be made of~~ the conformity of the pressure equipment ~~with~~ ☒ to ☒ the ☒ relevant ☒ requirements ⇒, and shall include an adequate analysis and assessment of the risk(s). ⇐

~~☒~~ The technical documentation shall specify the applicable requirements and cover, ~~☒~~ of the Directive which apply to it. It must, as far as is relevant for such ~~☒~~ the ~~☒~~ assessment, cover the design, manufacture and operation of the pressure equipment. ~~☒~~ The technical documentation shall, wherever applicable, ~~☒~~ and contain ~~☒~~ at least the following elements ~~☒~~ :

↓ 97/23/EC

- a general description of the pressure equipment₂;

↓ 97/23/EC (adapted)

⇒ new

- conceptual design and manufacturing drawings and ~~diagrams~~ ~~☒~~ schemes ~~☒~~ of components, sub-assemblies, circuits, etc.₂;
- descriptions and explanations necessary for an understanding of the ~~said~~ ~~☒~~ those ~~☒~~ drawings and ~~diagrams~~ ~~☒~~ schemes ~~☒~~ and the operation of the pressure equipment₂;
- a list of the ~~☒~~ harmonised ~~☒~~ standards referred to in Article 5 ~~☒~~ the references of which have been published in the *Official Journal of the European Union* ~~☒~~, applied in full or in part, and a description of the solutions adopted to meet the essential ~~☒~~ safety ~~☒~~ requirements of the ~~☒~~ this ~~☒~~ Directive where the ~~☒~~ those harmonised ~~☒~~ standards referred to in Article 5 have not been applied₂. ⇒ In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied; ⇐

↓ 97/23/EC

- results of design calculations made, examinations carried out, etc.₂;
- test reports.

~~4. The manufacturer, or his authorized representative established within the Community, must keep a copy of the declaration of conformity with the technical documentation.~~

↓ 97/23/EC (adapted)

⇒ new

53. ~~☒~~ Manufacturing ~~☒~~

The manufacturer ~~must~~ ~~☒~~ shall ~~☒~~ take all measures necessary to ensure ~~☒~~ so ~~☒~~ that the manufacturing process ~~⇒~~ and its monitoring ~~⇐~~ ~~☒~~ ensure compliance of ~~☒~~ requires the manufactured pressure equipment to comply with the technical documentation referred to in section point 2 and with the requirements of the ~~☒~~ this ~~☒~~ Directive which apply to it.

~~☒~~ 4. CE marking and EU declaration of conformity ~~☒~~

4.1. The manufacturer, ~~or his authorized representative established within the Community,~~ ~~must~~ ~~☒~~ shall ~~☒~~ affix the CE marking to each ~~item~~ ~~☒~~ individual ~~☒~~ of pressure equipment

~~and draw up a written declaration of conformity~~ ☒ that satisfies the applicable requirements of this Directive ☒ .

↓ new

4.2. The manufacturer shall draw up a written EU declaration of conformity for the pressure equipment model and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the pressure equipment has been placed on the market. The EU declaration of conformity shall identify the pressure equipment for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

5. Authorised representative

The manufacturer's obligations set out in point 4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

↓ 97/23/EC

~~MODULE A1 (INTERNAL MANUFACTURING CHECKS WITH MONITORING OF THE FINAL ASSESSMENT)~~

~~In addition to the requirements of module A, the following applies:~~

~~Final assessment must be performed by the manufacturer and monitored by means of unexpected visits by a notified body chosen by the manufacturer.~~

~~During such visits, the notified body must:~~

~~— establish that the manufacturer actually performs final assessment in accordance with section 3.2 of Annex I;~~

~~— take samples of pressure equipment at the manufacturing or storage premises in order to conduct checks. The notified body assesses the number of items of equipment to sample and whether it is necessary to perform, or have performed, all or part of the final assessment of the pressure equipment samples.~~

~~Should one or more of the items of pressure equipment not conform, the notified body must take appropriate measures.~~

~~On the responsibility of the notified body, the manufacturer must affix the former's identification number on each item of pressure equipment.~~

2. MODULE A2: INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRESSURE EQUIPMENT CHECKS AT RANDOM INTERVALS

1. Internal production control plus final assessment performed by the manufacturer and monitored by means of unexpected visits by a notified body chosen by the manufacturer is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3, 4, and 5, and ensures and declares on his sole responsibility that the pressure equipment concerned satisfy the requirements of this Directive.

2. Technical documentation

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the conformity of the pressure equipment with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the pressure equipment. The technical documentation shall contain, wherever applicable, at least the following elements:

- a general description of the pressure equipment;
- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;
- descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the pressure equipment;
- a list of the harmonised standards the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;
- results of design calculations made, examinations carried out, etc., and
- test reports.

3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured pressure equipment with the technical documentation referred to in point 2 and with the requirements of this Directive that apply to it.

4. Final assessment and pressure equipment checks

The manufacturer shall perform a final assessment of the pressure equipment, monitored by means of unexpected visits by a notified body chosen by the manufacturer.

The notified body shall carry out product checks or have them carried out at random intervals determined by the body, in order to verify the quality of the internal checks of the pressure equipment, taking into account inter alia the technological complexity of the pressure equipment and the quantity of production.

During its unexpected visits, the notified body shall:

- establish that the manufacturer actually performs final assessment in accordance with point 3.2 of Annex I.
- take samples of pressure equipment at the manufacturing or storage premises in order to conduct checks. The notified body assesses the number of items of equipment to sample and whether it is necessary to perform, or have performed, all or part of the final assessment of the pressure equipment samples.

The acceptance sampling procedure to be applied is intended to determine whether the manufacturing process of the pressure equipment performs within acceptable limits, with a view to ensuring conformity of the pressure equipment.

Should one or more of the items of pressure equipment or assembly not conform, the notified body shall take appropriate measures.

The manufacturer shall, under the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.

5. CE marking and EU declaration of conformity

5.1. The manufacturer shall affix the CE marking to each individual pressure equipment that satisfies the applicable requirements of this Directive.

5.2. The manufacturer shall draw up a written EU declaration of conformity for the pressure equipment model and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the pressure equipment has been placed on the market. The EU declaration of conformity shall identify the pressure equipment for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

6. Authorised representative

The manufacturer's obligations set out in point 5 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

↓ 97/23/EC (adapted)

3. MODULE B: ~~(EC-TYPE)~~ ☒ EU-TYPE ☒ EXAMINATION

☒ 3.1. EU-type examination – combination of production type and design type ☒

↓ 97/23/EC

~~1. This module describes the part of the procedure by which a notified body ascertains and attests that a representative example of the production in question meets the provisions of the Directive which apply to it.~~

~~2. The application for EC type-examination must be lodged by the manufacturer or by his authorized representative established within the Community with a single notified body of his choice.~~

↓ new

1. EU-type examination - combination of production type and design type is the part of a conformity assessment procedure in which a notified body examines the technical design of the pressure equipment and verifies and attests that the technical design of the pressure equipment meets the requirements of this Directive.

2. EU-type examination - combination of production type and design type shall consist of an assessment of the adequacy of the technical design of the pressure equipment through examination of the technical documentation and supporting evidence referred to in point 3, plus examination of specimens, representative of the production envisaged, of one or more critical parts of the pressure equipment.

3. The manufacturer shall lodge an application for EU-type examination with a single notified body of his choice.

↓ 97/23/EC (adapted)

The application ~~must~~ ☒ shall ☒ include:

↓ 97/23/EC

- the name and address of the manufacturer and, if the application is lodged by the authorized representative, his name and address as well₂;
 - a written declaration that the same application has not been lodged with any other notified body₂;
-

↓ 97/23/EC (adapted)

- ~~the technical documentation described in section 3.~~
-

↓ 97/23/EC

~~The applicant must place at the disposal of the notified body a representative example of the production envisaged, hereinafter called «type». The notified body may request further examples should the test programme so require.~~

~~A type may cover several versions of pressure equipment provided that the differences between the versions do not affect the level of safety.~~

↓ 97/23/EC (adapted)

⇒ new

- ~~3.~~ ~~☒~~ the technical documentation. ~~☒~~ The technical documentation ~~must enable~~ ~~☒~~ shall make it possible to ~~☒~~ ~~an assessment to be made of~~ the conformity of the pressure equipment with the ~~☒~~ applicable ~~☒~~ requirements of ~~the~~ ~~☒~~ this ~~☒~~ Directive ~~⇒~~ and shall include an adequate analysis and assessment of the risk(s). ~~☒~~ ~~which apply to it. It must~~ ~~☒~~ The technical documentation shall specify the applicable requirements and cover ~~☒~~, as far as ~~is~~ relevant for ~~such~~ ~~☒~~ the ~~☒~~ assessment, ~~cover~~ the design, manufacture and operation of the pressure equipment. ~~☒~~ The technical documentation shall ~~☒~~ ~~and~~ contain ~~☒~~, wherever applicable, at least the following elements ~~☒~~ :
 - a general description of the ~~type~~ ~~☒~~ pressure equipment ~~☒~~ ~~;~~
 - conceptual design and manufacturing drawings and ~~diagrams~~ ~~☒~~ schemes ~~☒~~ of components, sub-assemblies, circuits, etc. ~~;~~

↓ 97/23/EC (adapted)

⇒ new

- descriptions and explanations necessary for ~~an~~ ~~☒~~ the ~~☒~~ understanding of ~~the~~ ~~☒~~ those ~~☒~~ ~~said~~ drawings and ~~diagrams~~ ~~☒~~ schemes ~~☒~~ and the operation of the pressure equipment ~~;~~
- a list of the ~~☒~~ harmonised ~~☒~~ standards ~~referred to in Article 5~~ ~~☒~~ the references of which have been published in the *Official Journal of the European Union* ~~☒~~, applied in full or in part, and descriptions of the solutions adopted to meet the essential ~~☒~~ safety ~~☒~~ requirements of ~~the~~ ~~☒~~ this ~~☒~~ Directive where ~~the~~ ~~☒~~ those harmonised ~~☒~~ standards ~~referred to in Article 5~~ have not been applied. ~~☒~~ ~~⇒~~ In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied; ~~☒~~

↓ 97/23/EC

- results of design calculations made, examinations carried out, etc. ~~;~~
- test reports ~~;~~
- information concerning the tests provided for in manufacture ~~;~~
- information concerning the qualifications or approvals required under sections points 3.1.2 and 3.1.3 of Annex I ~~;~~

↓ new

- the specimens representative of the production envisaged;

The specimen may cover several versions of the pressure equipment provided that the differences between the versions do not affect the level of safety.

The notified body may request further specimens if needed for carrying out the test programme;

- the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer applying other relevant technical specifications, or by another testing laboratory on his behalf and under his responsibility.

↓ 97/23/EC (adapted)
⇒ new

4. The notified body ~~must~~ ☒ shall ☒ :

4.1. examine the technical documentation, ~~verify that the type has been manufactured in conformity with it and identify the components designed in accordance with the relevant provisions of the standards referred to in Article 5, as well as those designed without applying the provisions of those standards~~ ⇒ and supporting evidence to assess the adequacy of the technical design of the pressure equipment and the manufacturing procedures ⇐ .

In particular, the notified body ~~must~~ ☒ shall ☒:

- ~~examine the technical documentation with respect to the design and the manufacturing procedures,~~
- assess the materials ~~used~~ where these are not in conformity with the relevant harmonised standards or with a European approval for pressure equipment materials, and check the certificate issued by the material manufacturer in accordance with section point 4.3 of Annex I₂;

↓ 97/23/EC

- approve the procedures for the permanent joining of pressure equipment parts, or check that they have been previously approved in accordance with section point 3.1.2 of Annex I₂;
- verify that the personnel undertaking the permanent joining of pressure equipment parts and the non-destructive tests are qualified or approved in accordance with sections points 3.1.2 or 3.1.3 of Annex I.

~~4.2. perform or have performed the appropriate examinations and necessary tests to establish whether the solutions adopted by the manufacturer meet the essential requirements of the Directive where the standards referred to in Article 5 have not been applied.~~

↓ new

4.2. verify that the specimen(s) have been manufactured in conformity with the technical documentation and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards as well as the elements which have been designed using other relevant technical specifications without applying the relevant provisions of those standards.

↓ 97/23/EC (adapted)

4.3. ~~perform or have performed the~~ ☒ carry out ☒ appropriate examinations ~~and necessary tests to establish whether,~~ ☒ to check ☒ ~~where~~ ☒ whether when ☒ the manufacturer has chosen to apply ☒ the solutions in ☒ the relevant ☒ harmonised ☒ standards, these have ~~actually~~ been applied ☒ correctly ☒.

↓ new

4.4. carry out appropriate examinations to check whether, where the solutions in the relevant harmonised standards have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential safety requirements of this Directive.

4.5. agree with the manufacturer on a location where the examinations and tests will be carried out.

↓ 97/23/EC

~~4.4. agree with the applicant the location where the examinations and necessary tests are to be carried out.~~

~~5. Where the type satisfies the provisions of the Directive which apply to it, the notified body must issue an EC type-examination certificate to the applicant. The certificate, which should be valid for ten years and be renewable, must contain the name and address of the manufacturer, the conclusions of the examination and the necessary data for identification of the approved type.~~

~~A list of the relevant parts of the technical documentation must be annexed to the certificate and a copy kept by the notified body.~~

~~If the notified body refuses to issue an EC type-examination certificate to the manufacturer or to his authorized representative established within the Community, that body must provide detailed reasons for such refusal. Provision must be made for an appeals procedure.~~

~~6. The applicant must inform the notified body that holds the technical documentation concerning the EC type-examination certificate of all modifications to the approved pressure equipment; these are subject to additional approval where they may affect conformity with the essential requirements or the prescribed conditions for use of the pressure equipment. This additional approval must be given in the form of an addition to the original EC type-examination certificate.~~

~~7. Each notified body must communicate to the Member States the relevant information concerning EC type-examination certificates which it has withdrawn, and, on request, those it has issued.~~

~~Each notified body must also communicate to the other notified bodies the relevant information concerning the EC type-examination certificates it has withdrawn or refused.~~

~~8. The other notified bodies may receive copies of the EC type-examination certificates and/or their additions. The annexes to the certificates must be held at the disposal of the other notified bodies.~~

~~9. The manufacturer, or his authorized representative established within the Community, must keep with the technical documentation copies of EC type-examination certificates and their additions for a period of ten years after the last of the pressure equipment has been manufactured.~~

~~Where neither the manufacturer nor his authorized representative is established within the Community, the obligation to keep the technical documentation available is the responsibility of the person who places the product on the Community market.~~

↓ new

5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à-vis the notifying authority, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

6. Where the type meets the requirements of this Directive, the notified body shall issue an EU-type examination certificate – combination of production type and design type to the manufacturer. The certificate, which should be valid for 10 years and be renewable, shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type.

A list of the relevant parts of the technical documentation shall be annexed to the certificate and a copy kept by the notified body.

The certificate and its annexes shall contain all relevant information to allow the conformity of manufactured pressure equipment with the examined type to be evaluated and to allow for in-service control.

Where the type does not satisfy the applicable requirements of this Directive, the notified body shall refuse to issue an EU-type examination certificate – combination of production type and design type and shall inform the applicant accordingly, giving detailed reasons for its refusal. Provision shall be made for an appeals procedure.

7. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of this Directive, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-type examination certificate – production type of all modifications to the approved type that may affect the conformity of the pressure equipment with the essential safety requirements of this Directive or the conditions for validity of the certificate. Such modifications shall require additional approval in the form of an addition to the original EU-type examination certificate – production type.

8. Each notified body shall inform its notifying authority concerning the EU-type examination certificates – combination of production type and design type and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies concerning the EU-type examination certificates – combination of production type and design type and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning the certificates and/or additions thereto which it has issued.

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates – combination of production type and design type and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EU-type examination certificate – combination of production type and design type, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of the certificate.

9. The manufacturer shall keep a copy of the EU-type examination certificate – combination of production type and design type, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the pressure equipment has been placed on the market.

10. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9, provided that they are specified in the mandate.

↓ 97/23/EC (adapted)

MODULE B1 3.2. (EC DESIGN) EU-TYPE EXAMINATION – DESIGN TYPE

↓ 97/23/EC

~~1. This module describes the part of the procedure whereby a notified body ascertains and attests that the design of an item of pressure equipment meets the provisions of the Directive which apply to it.~~

↓ new

1. EU-type examination – design type is the part of a conformity assessment procedure in which a notified body examines the technical design of the pressure equipment and verifies

and attests that the technical design of the pressure equipment meets the requirements of this Directive.

2. The EU-type examination – design type shall consist of an assessment of the adequacy of the technical design of the pressure equipment through examination of the technical documentation and supporting evidence referred to in point 3, without examination of a specimen.

↓ 97/23/EC (adapted)

~~1.~~ The experimental design method provided for in ~~section point~~ 2.2.4 of Annex I ~~may~~ ☒ shall ☒ not be used in the context of this module.

~~23.~~ The manufacturer, ~~or his authorized representative established within the Community,~~ ~~must~~ ☒ shall ☒ lodge an application for ~~EC design~~ ☒ EU-type ☒ examination ☒ - design type ☒ with a single notified body ☒ of his choice ☒.

The application ~~must~~ ☒ shall ☒ include:

↓ 97/23/EC

- the name and address of the manufacturer and, if the application is lodged by the authorized representative, his name and address as well;
- a written declaration that the same application has not been lodged with any other notified body;

↓ 97/23/EC (adapted)

- ~~the technical documentation described in section 3.~~

↓ 97/23/EC

~~The application may cover several versions of the pressure equipment provided that the differences between the versions do not affect the level of safety.~~

↓ 97/23/EC (adapted)

⇒ new

- ~~3.~~ ☒ the technical documentation. ☒ The technical documentation ~~must enable an~~ ☒ shall make it possible to ☒ assessment ~~to be made of~~ the conformity of the pressure equipment with the ☒ applicable ☒ requirements of the Directive ~~which apply to it~~ ☒ and shall include an adequate analysis and assessment of the risk(s) ☒. ☒ The technical documentation shall specify the applicable requirements and cover ☒ ~~It must,~~ as far as is relevant for ~~such~~ ☒ the ☒ assessment, ~~cover~~ the design, manufacture and operation of the pressure equipment. ☒ The technical documentation shall ☒ ~~and~~ contain ☒, wherever applicable, at least the following elements ☒:

- a general description of the pressure equipment;

- conceptual design and manufacturing drawings and ~~diagrams~~ ☒ schemes ☒ of components, sub-assemblies, circuits, etc.³²;
- descriptions and explanations necessary for ~~an~~ ☒ the ☒ understanding of ~~the said~~ ☒ those ☒ drawings and ~~diagrams~~ ☒ schemes ☒ and the operation of the pressure equipment³²;
- a list of the ☒ harmonised ☒ standards ~~referred to in Article 5~~ ☒ the references of which have been published in the *Official Journal of the European Union* ☒, applied in full or in part, and descriptions of the solutions adopted to meet the essential ☒ safety ☒ requirements of ~~the~~ ☒ this ☒ Directive where ~~the~~ ☒ those harmonised ☒ standards ~~referred to in Article 5~~ ☒ have ☒ not been applied. \Rightarrow In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied; \Leftarrow

\Downarrow 97/23/EC

- results of design calculations made, examinations carried out, etc.³²;
- information regarding the qualifications or approvals required under sections points 3.1.2 and 3.1.3 of Annex I³²;

\Downarrow 97/23/EC (adapted)

\Rightarrow new

- the ~~necessary~~ supporting evidence for the adequacy of the ☒ technical ☒ design solution³². \Rightarrow This supporting evidence shall mention any documents that have been used, \Leftarrow in particular where the ☒ relevant harmonised ☒ standards ~~referred to in Article 5~~ have not been applied in full³². ~~the~~ ☒ This ☒ supporting evidence ~~must~~ ☒ shall ☒ include ☒ , where necessary, ☒ the results of tests carried out by the appropriate laboratory of the manufacturer or ☒ by another testing laboratory ☒ on his behalf ☒ and under his responsibility ☒ ³².

\Downarrow new

The application may cover several versions of the pressure equipment provided that the differences between the versions do not affect the level of safety.

\Downarrow 97/23/EC (adapted)

\Rightarrow new

4. The notified body ~~must~~ ☒ shall ☒.

4.1. examine the technical documentation ~~and identify the components which have been designed in accordance with the relevant provisions of the standards referred to in Article 5, as well as those which have been designed without applying the relevant provisions of those standards.~~ \Rightarrow and supporting evidence to assess the adequacy of the technical design of the product. \Leftarrow

In particular, the notified body ~~must~~ ☒ shall ☒:

↓ 97/23/EC

- assess the materials where these are not in conformity with the relevant harmonised standards or with a European approval for pressure equipment materials;
- approve the procedures for the permanent joining of pressure equipment parts, or check that they have been previously approved in accordance with section point 3.1.2 of Annex I;
- ~~verify that the personnel undertaking the permanent joining of pressure equipment parts and the non-destructive tests are qualified or approved in accordance with sections 3.1.2 and 3.1.3 of Annex I.~~

↓ 97/23/EC (adapted)

⇒ new

4.2. ~~perform the necessary~~ ☒ carry out appropriate ☒ examinations to ~~establish~~ ☒ check ☒ whether ☒ where the manufacturer has chosen to apply ☒ the solutions adopted by the manufacturer meet the essential requirements of the Directive where the standards referred to in Article 5 ☒ in the relevant harmonised standards these ☒ have ~~not~~ been applied ⇒ correctly ⇐ .

4.3. ~~perform the necessary~~ ☒ carry out appropriate ☒ examinations to ~~establish~~ ☒ check ☒ whether, where the manufacturer has chosen to apply the relevant standards, ~~these have actually been applied~~ ☒ solutions in the relevant harmonised standards have not been applied, the solutions adopted by the manufacturer meet the corresponding essential safety requirements of this Directive ☒ .

↓ 97/23/EC

~~5. Where the design meets the provisions of the Directive which apply to it, the notified body must issue an EC design examination certificate to the applicant. The certificate must contain the name and address of the applicant, the conclusions of the examination, conditions for its validity and the necessary data for identification of the approved design.~~

~~A list of the relevant parts of the technical documentation must be annexed to the certificate and a copy kept by the notified body.~~

~~If the notified body refuses to issue an EC design examination certificate to the manufacturer or to his authorized representative established within the Community, that body must provide detailed reasons for such refusal. Provision must be made for an appeals procedure.~~

~~6. The applicant must inform the notified body that holds the technical documentation concerning the EC design examination certificate of all modifications to the approved design; these are subject to additional approval where such changes may affect the conformity of the pressure equipment with the essential requirements of the Directive or the prescribed conditions for use of the equipment. This additional approval must be given in the form of an addition to the original EC design examination certificate.~~

~~7. Each notified body must communicate to the Member States the relevant information concerning EC design examination certificates which it has withdrawn, and, on request, those it has issued.~~

~~Each notified body must also communicate to the other notified bodies the relevant information concerning the EC design examination certificates it has withdrawn or refused.~~

~~8. The other notified bodies may on request obtain the relevant information concerning:~~

~~the EC design examination certificates and additions granted,~~

~~the EC design examination certificates and additions withdrawn.~~

~~9. The manufacturer, or his authorized representative established within the Community, must keep with the technical documentation referred to in section 3 copies of EC design examination certificates and their additions for a period of ten years after the last of the pressure equipment has been manufactured.~~

~~Where neither the manufacturer nor his authorized representative is established within the Community, the obligation to keep the technical documentation available is the responsibility of the person who places the product on the Community market.~~

↓ new

5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à-vis the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

6. Where the design meets the requirements of this Directive, the notified body shall issue an EU-type examination certificate - design type to the manufacturer. The certificate, which should be valid for 10 years and be renewable, shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved design.

A list of the relevant parts of the technical documentation shall be annexed to the certificate and a copy kept by the notified body.

The certificate and its annexes shall contain all relevant information to allow the conformity of manufactured pressure equipment with the examined design to be evaluated and to allow for in-service control.

Where the design does not satisfy the applicable requirements of this Directive, the notified body shall refuse to issue an EU-type examination certificate - design type and shall inform the applicant accordingly, giving detailed reasons for its refusal.

7. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved design may no longer comply with the applicable requirements of this Directive, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-type examination certificate - design type of all modifications to the approved design that may affect the conformity of the pressure equipment with the essential safety requirements of this Directive or the conditions for validity of the certificate. Such modifications shall require additional approval in the form of an addition to the original EU-type examination certificate - design type.

8. Each notified body shall inform its notifying authorities concerning the EU-type examination certificates - design type and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies concerning the EU-type examination certificates - design type and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning the certificates and/or additions thereto which it has issued.

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates - design type and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EU-type examination certificate - design type, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of the certificate.

9. The manufacturer shall keep a copy of the EU-type examination certificate - design type, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the pressure equipment has been placed on the market.

10. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9, provided that they are specified in the mandate.

↓ 97/23/EC (adapted)

4. MODULE ~~C12~~: ~~(CONFORMITY TO TYPE)~~ ☒ BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRESSURE EQUIPMENT CHECKS AT RANDOM INTERVALS ☒

↓ 97/23/EC

~~1. This module describes that part of the procedure whereby the manufacturer, or his authorized representative established within the Community, ensures and declares that pressure equipment is in conformity with the type as described in the EC type examination certificate and satisfies the requirements of the Directive which apply to it. The manufacturer, or his authorized representative established within the Community, must affix the CE marking to each item of pressure equipment and draw up a written declaration of conformity.~~

↓ new

1. Conformity to type based on internal production control plus supervised pressure equipment checks at random intervals is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that the pressure equipment concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to it.

↓ 97/23/EC (adapted)

⇒ new

2. ☒ Manufacturing ☒

The manufacturer ~~must~~ ☒ shall ☒ take all measures necessary ~~to ensure~~ ☒ so ☒ that the manufacturing process ☒ and its monitoring ensure conformity of ☒ ~~requires~~ the manufactured pressure equipment ~~to comply~~ with the type as described in the ~~EC type-~~ ☒ EU-type ☒ examination certificate and with the requirements of ~~the~~ ☒ this ☒ Directive ~~which~~ ☒ that ☒ apply to ~~it~~ ☒ them ☒.

↓ 97/23/EC

~~3. The manufacturer, or his authorized representative established within the Community, must keep a copy of the declaration of conformity for a period of ten years after the last of the pressure equipment has been manufactured.~~

~~Where neither the manufacturer nor his authorized representative is established within the Community, the obligation to keep the technical documentation available is the responsibility of the person who places the pressure equipment on the Community market.~~

~~4. Final assessment must be subject to monitoring in the form of unexpected visits by a notified body chosen by the manufacturer.~~

~~During such visits, the notified body must:~~

~~— establish that the manufacturer actually performs final assessment in accordance with section 3.2 of Annex I,~~

~~— take samples of pressure equipment at the manufacturing or storage premises in order to conduct checks. The notified body must assess the number of items of equipment to sample and whether it is necessary to perform, or have performed, all or part of final assessment on the pressure equipment samples.~~

~~Should one or more of the items of pressure equipment not conform, the notified body must take appropriate measures.~~

~~On the responsibility of the notified body, the manufacturer must affix the former's identification number on each item of pressure equipment.~~

3. Final assessment and pressure equipment checks

A notified body, chosen by the manufacturer, shall carry out checks or have them carried out at random intervals determined by the body, in order to verify the quality of the final assessment and of the internal checks on the pressure equipment, taking into account inter alia the technological complexity of the pressure equipment and the quantity of production.

The notified body shall establish that the manufacturer actually performs final assessment in accordance with point 3.2 of Annex I.

An adequate sample of the final pressure equipment, taken on site by the notified body before the placing on the market, shall be examined and appropriate tests as identified by the relevant parts of the harmonised standards, and/or equivalent tests applying other technical specifications, shall be carried out to check the conformity of the pressure equipment with the relevant requirements of this Directive.

The notified body shall assess the number of items of equipment to sample and whether it is necessary to perform, or have performed, all or part of final assessment on the pressure equipment samples.

Where a sample does not conform to the acceptable quality level, the body shall take appropriate measures.

The acceptance sampling procedure to be applied is intended to determine whether the manufacturing process of the pressure equipment performs within acceptable limits, with a view to ensuring conformity of the pressure equipment.

Where the tests are carried out by a notified body, the manufacturer shall, under the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.

4. CE marking and EU declaration of conformity

4.1. The manufacturer shall affix the CE marking to each individual pressure equipment or assembly that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

4.2. The manufacturer shall draw up a written EU declaration of conformity for a pressure equipment model and keep it at the disposal of the national authorities for 10 years after the pressure equipment has been placed on the market. The EU declaration of conformity shall identify the pressure equipment model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

5. Authorised representative

The manufacturer's obligations set out in point 4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

↓ 97/23/EC (adapted)

5. MODULE D: ~~€~~ ☒ CONFORMITY TO TYPE BASED ON ☒ ~~PRODUCTION~~ QUALITY ASSURANCE ☒ OF THE PRODUCTION PROCESS ☒

↓ 97/23/EC

~~1. This module describes the procedure whereby the manufacturer who satisfies the obligations of section 2 ensures and declares that the pressure equipment concerned is in conformity with the type described in the EC type-examination certificate or EC design-examination certificate and satisfies the requirements of the Directive which apply to it. The manufacturer, or his authorized representative established within the Community, must affix the CE marking to each item of pressure equipment and draw up a written declaration of conformity. The CE marking must be accompanied by the identification number of the notified body responsible for surveillance as specified in section 4.~~

↓ new

1. Conformity to type based on quality assurance of the production process is that part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the pressure equipment or assembly concerned is in conformity with the type described in the EU-type examination certificate and satisfies the requirements of this Directive that apply to it.

↓ 97/23/EC (adapted)

2. ☒ Manufacturing ☒

The manufacturer ~~must~~ ☒ shall ☒ operate an approved quality system for production, final ☒ product ☒ inspection and testing ☒ of the pressure equipment concerned ☒ as specified in section point 3 and ☒ shall ☒ be subject to surveillance as specified in section point 4.

3. Quality system

3.1. The manufacturer ~~must~~ ☒ shall ☒ lodge an application for assessment of his quality system with ~~a~~ ☒ the ☒ notified body of his choice ☒ for the pressure equipment concerned ☒.

The application ~~must~~ ☒ shall ☒ include:

↓ new

– the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;

- a written declaration that the same application has not been lodged with any other notified body;

↓ 97/23/EC (adapted)

⇒ new

- all relevant information on the pressure equipment ⇒ type envisaged ⇐ concerned;
- the documentation concerning the quality system;
- the technical documentation for ☒ of ☒ the approved type and a copy of the ~~EC type~~ ☒ EU-type ☒ examination certificate ~~or EC design examination certificate~~.

3.2. The quality system ~~must~~ ☒ shall ☒ ensure ☒ that ☒ ~~compliance~~ of the pressure equipment ☒ is in conformity ☒ with the type described in the ~~EC type~~ ☒ EU-type ☒ examination certificate ~~or EC design examination certificate and~~ ☒ and comply ☒ with the requirements of ~~the~~ ☒ this ☒ Directive ~~which~~ ☒ that ☒ apply to it.

All the elements, requirements and provisions adopted by the manufacturer ~~must~~ ☒ shall ☒ be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation ~~must~~ ☒ shall ☒ permit a consistent interpretation of the quality programmes, plans, manuals and records.

It ~~must~~ ☒ shall ☒ ~~contain~~, in particular, ☒ contain ☒ an adequate description of:

↓ 97/23/EC

- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to the quality of the pressure equipment;

↓ 97/23/EC (adapted)

- the ☒ corresponding ☒ manufacturing, quality control and quality assurance techniques, processes and systematic ~~measures~~ ☒ actions ☒ that will be used, particularly the procedures used for the permanent joining of parts as approved in accordance with section point 3.1.2 of Annex I;

↓ 97/23/EC

- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;

↓ 97/23/EC (adapted)

- the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications or approvals of the personnel concerned, particularly those of the personnel undertaking the ☒ permanent ☒ joining of parts and the non-destructive tests in accordance with sections points 3.1.2 and 3.1.3 of Annex I, ☒ etc. and ☒

↓ 97/23/EC

- the means of monitoring the achievement of the required quality and the effective operation of the quality system.
-

↓ 97/23/EC (adapted)

3.3. The notified body ~~must~~ ☒ shall ☒ assess the quality system to determine whether it satisfies the requirements referred to in 3.2.

↓ new

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the national standard that implements the relevant harmonised standard.

↓ 97/23/EC (adapted)

⇒ new

~~The elements of the quality system which conform to the relevant harmonized standard are presumed to comply with the corresponding requirements referred to in 3.2.~~

☒ In addition to experience in quality management systems, ☒ ~~the~~ auditing team ~~must~~ ☒ shall ☒ have at least one member with experience of ~~assessing~~ ☒ evaluation in ☒ the ☒ relevant ☒ pressure equipment ☒ field and pressure equipment ☒ technology concerned ⇒ , and knowledge of the applicable requirements of this Directive ⇐ . The ~~assessment procedure must~~ ☒ audit shall ☒ include an inspection visit to the manufacturer's premises.

↓ new

The auditing team shall review the technical documentation referred to in point 3.1, fifth indent, to verify the manufacturer's ability to identify the relevant requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements.

↓ 97/23/EC (adapted)

The decision ~~must~~ ☒ shall ☒ be notified to the manufacturer. The notification ~~must~~ ☒ shall ☒ contain the conclusions of the ~~examination~~ ☒ audit ☒ and the reasoned assessment decision. ~~Provision must be made for an appeals procedure.~~

3.4. The manufacturer ~~must~~ ☒ shall ☒ undertake to fulfil the obligations arising out of the quality system as approved and to ~~ensure~~ ☒ maintain it so ☒ that it remains ~~satisfactory~~ ☒ adequate ☒ and efficient.

3.5. The manufacturer, ~~or his authorized representative established within the Community,~~ ~~must inform~~ ☒ shall keep ☒ the notified body that has approved the quality system ☒ informed ☒ of any intended ~~adjustment~~ ☒ change ☒ to the quality system.

The notified body ~~must~~ shall assess evaluate the proposed changes and decide whether the ~~amended~~ modified quality system will ~~still~~ continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is ~~required~~ necessary .

It ~~must~~ shall notify ~~its decision to~~ the manufacturer of its decision. The notification ~~must~~ shall contain the conclusions of the examination and the reasoned assessment decision.

↓ 97/23/EC

4. Surveillance under the responsibility of the notified body

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

↓ 97/23/EC (adapted)

4.2. The manufacturer ~~must~~ shall, for assessment purposes, allow the notified body access ~~for inspection purposes~~ to the ~~locations of~~ manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:

- the quality system documentation;
- the quality records, such as inspection reports and test data, calibration data, qualification reports ~~concerning the qualifications~~ of the personnel concerned, etc.

4.3. The notified body ~~must~~ shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and provide the manufacturer with an audit report. The frequency of periodic audits ~~must~~ shall be such that a full reassessment is carried out every three years.

4.4. In addition the notified body may pay unexpected visits to the manufacturer. The need for such additional visits, and the frequency thereof, will be determined on the basis of a visit control system operated by the notified body. In particular, the following factors ~~must~~ shall be considered in the visit control system:

- the category of the pressure equipment;

↓ 97/23/EC

- the results of previous surveillance visits;

↓ 97/23/EC (adapted)

- the need to follow up corrective ~~action~~ actions;

↓ 97/23/EC

- special conditions linked to the approval of the system, where applicable;

- significant changes in manufacturing organisation, policy or techniques.

↓ 97/23/EC (adapted)

During such visits the notified body may, if necessary, carry out ☒ product tests ☒ or have ☒ them ☒ carried out tests ☒ in order ☒ to verify that the quality system is functioning correctly. The notified body ~~must~~ ☒ shall ☒ provide the manufacturer with a visit report and, if ~~a test has taken place~~ ☒ tests have been carried out ☒ , with a test report.

↓ new

5. CE marking and EU declaration of conformity

5.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual pressure equipment that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

5.2. The manufacturer shall draw up a written EU declaration of conformity for each pressure equipment model and keep it at the disposal of the national authorities for 10 years after the pressure equipment has been placed on the market. The EU declaration of conformity shall identify the pressure equipment model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

↓ 97/23/EC (adapted)

⇒ new

~~5.6.~~ The manufacturer ~~must~~ ☒ shall ☒, for a period of ☒ ending ☒ ~~ten~~ 10 years after the last of the pressure equipment has been ~~manufactured~~ ⇒ placed on the market ⇐ , ~~hold~~ ☒ keep ☒ at the disposal of the national authorities:

↓ 97/23/EC

- the documentation referred to ~~in the second indent of point 3.1;~~

↓ 97/23/EC (adapted)

⇒ new

- the ~~adjustments~~ ☒ change ☒ referred to in ~~the second paragraph of point 3.45~~ ☒ , as approved ☒ ~~5.3~~
- the decisions and reports ~~from~~ ☒ of ☒ the notified body ~~which are~~ referred to in ~~the last paragraph of points 3.3, the last paragraph of 3.45, and in~~ 4.3 and 4.4.

~~6.7.~~ Each notified body ~~must communicate~~ ☒ shall inform ☒ ~~to the Member States the relevant information concerning~~ ⇒ its notifying authorities of ⇐ the quality system approvals ~~which it has~~ ☒ issued or ☒ withdrawn, and ☒ shall ☒ ⇐ , periodically or ⇐ , ~~on~~

☒ upon ☒ request, ~~those it has issued~~ ⇒ make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted ⇐ .

Each notified body ~~must~~ ☒ shall ☒ ~~also communicate to~~ ☒ inform ☒ the other notified bodies ~~the relevant information concerning~~ ☒ of ☒ the quality system approvals ☒ which ☒ it has ☒ refused, suspended, ☒ withdrawn or ~~refused~~ ⇒ otherwise restricted, and, upon request, of quality system approvals which it has issued ⇐ .

⇓ new

8. Authorised representative

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

⇓ 97/23/EC (adapted)

6. MODULE D1: ~~(PRODUCTION QUALITY ASSURANCE)~~ ☒ OF THE PRODUCTION PROCESS ☒

⇓ 97/23/EC

~~1. This module describes the procedure whereby the manufacturer who satisfies the obligations of section 3 ensures and declares that the items of pressure equipment concerned satisfy the requirements of the Directive which apply to them. The manufacturer, or his authorized representative established within the Community, must affix the CE marking to each item of pressure equipment and draw up a written declaration of conformity. The CE marking must be accompanied by the identification number of the notified body responsible for surveillance as specified in section 5.~~

⇓ new

1. Quality assurance of the production process is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 4 and 7, and ensures and declares on his sole responsibility that the pressure equipment concerned satisfy the requirements of this Directive that apply to it.

⇓ 97/23/EC (adapted)

⇓ new

2. ~~The manufacturer must draw up the~~ Technical documentation described below.

⇒ The manufacturer shall establish the technical documentation. ⇐ The ~~technical~~ documentation ~~must~~ ☒ shall ☒ ~~enable~~ ☒ make it possible to assess ☒ ~~an assessment to be made of~~ the conformity of the pressure equipment with the ☒ relevant ☒ requirements of the Directive which apply to it ⇒ and shall include an adequate analysis and assessment of the risk(s) ⇐ . ~~It must,~~ ⇒ The technical documentation shall specify the applicable requirements ⇐ ☒ and cover, ☒ as far as is relevant for ~~such~~ ☒ the ☒ assessment, ~~cover~~ the design, manufacture and operation of the ~~pressure equipment~~ ☒ product. The technical

documentation shall, wherever applicable, ~~and~~ contain at least the following elements :

↓ 97/23/EC

- a general description of the pressure equipment ~~is~~;

↓ 97/23/EC (adapted)

⇒ new

- conceptual design and manufacturing drawings and ~~diagrams~~ schemes of components, sub-assemblies, circuits, etc.;
- descriptions and explanations necessary for an understanding of ~~the~~ those ~~said~~ drawings and ~~diagrams~~ schemes and the operation of the pressure equipment ~~is~~;
- a list of the harmonised standards ~~referred to in Article 5~~ the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of ~~the~~ this Directive where ~~the~~ those harmonised standards ~~referred to in Article 5~~ have not been applied. ⇒ In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied; ⇐
- results of design calculations made, examinations carried out, etc., and
- test reports.

↓ new

3. The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the pressure equipment has been placed on the market.

↓ 97/23/EC (adapted)

34. Manufacturing

The manufacturer ~~must~~ shall operate an approved quality system for production, final product inspection and testing of the pressure equipment concerned as specified in ~~section 4~~ point 5, and shall be subject to surveillance as specified in ~~section 5~~ point 6.

45. Quality system

45.1. The manufacturer ~~must~~ shall lodge an application for assessment of his quality system with ~~a~~ the notified body of his choice for the pressure equipment concerned .

The application ~~must~~ shall include:

↓ new

- the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
 - a written declaration that the same application has not been lodged with any other notified body;
-

↓ 97/23/EC (adapted)

- all relevant information on the pressure equipment ☒ type envisaged ☒ concerned_{3.2};
 - the documentation concerning the quality system_{3.2};
-

↓ new

- the technical documentation referred to in point 2.
-

↓ 97/23/EC (adapted)

45.2. The quality system ~~must~~ ☒ shall ☒ ensure compliance of the pressure equipment with the requirements of ~~the~~ ☒ this ☒ Directive ~~which~~ ☒ that ☒ apply to it.

All the elements, requirements and provisions adopted by the manufacturer ~~must~~ ☒ shall ☒ be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation ~~must~~ ☒ shall ☒ permit a consistent interpretation of the quality programmes, plans, manuals and records.

It ~~must~~ ☒ shall, in particular, ☒ contain ~~in particular~~ an adequate description of:

↓ 97/23/EC

- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to the quality of the pressure equipment_{3.2};
-

↓ 97/23/EC (adapted)

- the ☒ corresponding ☒ manufacturing, quality control and quality assurance techniques, processes and systematic measures that will be used, particularly the procedures used for the permanent joining of parts as approved in accordance with section point 3.1.2 of Annex I_{3.2};
-

↓ 97/23/EC

- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out_{3.2};

↓ 97/23/EC (adapted)

⇒ new

- the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications or approvals of the personnel concerned, particularly those of the personnel undertaking the permanent joining of parts in accordance with section point 3.1.2 of Annex I, ☒ etc.; ☒
- the means of monitoring the achievement of the required ☒ product ☒ quality and the effective operation of the quality system.

45.3. The notified body ~~must~~ ☒ shall ☒ assess the quality system to determine whether it satisfies the requirements referred to in 45.2. The elements of the quality system which conform to the relevant harmonised standard are presumed to comply with the corresponding requirements referred to in 45.2.

☒ In addition to experience in quality management systems, ☒ ~~The~~ the auditing team ~~must~~ ☒ shall ☒ have at least one member with experience of ~~assessing~~ ☒ evaluation in ☒ the pressure equipment technology concerned ⇒ , and the knowledge of the applicable requirements of this Directive ⇐ . ~~The assessment procedure~~ ☒ audit ☒ ~~must~~ ☒ shall ☒ include an ~~inspection~~ ☒ assessment ☒ visit to the manufacturer's premises.

↓ new

The auditing team shall review the technical documentation referred to in point 2 in order to verify the manufacturer's ability to identify the relevant requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the pressure equipment with those requirements.

↓ 97/23/EC (adapted)

The decision ~~must~~ ☒ shall ☒ be notified to the manufacturer. The notification ~~must~~ ☒ shall ☒ contain the conclusions of the ~~examination~~ ☒ audit ☒ and the reasoned assessment decision. ~~Provision must be made for an appeals procedure.~~

45.4. The manufacturer ~~must~~ ☒ shall ☒ undertake to fulfil the obligations arising out of the quality system as approved and to ~~ensure~~ ☒ maintain it so ☒ that it remains ~~satisfactory~~ ☒ adequate ☒ and efficient.

5.5. The manufacturer, ~~or his authorized representative established within the Community,~~ ~~must inform~~ ☒ shall keep ☒ the notified body that has approved the quality system ☒ informed ☒ of any intended ~~adjustment~~ ☒ change ☒ to the quality system.

The notified body ~~must assess~~ ☒ shall evaluate ☒ ~~the~~ ☒ any ☒ proposed changes and decide whether the ~~amended~~ ☒ modified ☒ quality system will ~~still~~ ☒ continue to ☒ satisfy the requirements referred to in point 45.2 or whether a reassessment is ~~required~~ ☒ necessary ☒ .

If ~~must~~ ☒ shall ☒ notify ~~its decision to~~ the manufacturer ☒ of its decision ☒ . The notification ~~must~~ ☒ shall ☒ contain the conclusions of the examination and the reasoned assessment decision.

↓ 97/23/EC

56. Surveillance under the responsibility of the notified body

56.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

↓ 97/23/EC (adapted)

56.2. The manufacturer ~~must~~ ☒ shall, for assessment purposes, ☒ allow the notified body access ~~for inspection purposes~~ to the ~~locations of~~ manufacture, inspection, testing and storage ☒ sites ☒ and ☒ shall ☒ provide it with all necessary information, in particular:

- the quality system documentation_{5.2}
-

↓ new

- the technical documentation referred to in point 2;
-

↓ 97/23/EC (adapted)

- the quality records, such as inspection reports and test data, calibration data, ~~reports concerning the qualifications~~ ☒ reports ☒ of the personnel concerned, etc.

56.3. The notified body ~~must~~ ☒ shall ☒ carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and provide the manufacturer with an audit report. The frequency of periodic audits ~~must~~ ☒ shall ☒ be such that a full reassessment is carried out every three years.

56.4. In addition the notified body may pay unexpected visits to the manufacturer. The need for such additional visits, and the frequency thereof, will be determined on the basis of a visit control system operated by the notified body. In particular, the following factors ~~must~~ ☒ shall ☒ be considered in the visit control system:

- the category of the ☒ pressure ☒ equipment_{5.2}
-

↓ 97/23/EC

- the results of previous surveillance visits_{5.2}
- the need to follow up corrective action(s)_{5.2}
- special conditions linked to the approval of the system, where applicable_{5.2}
- significant changes in manufacturing organization, policy or techniques.

↓ 97/23/EC (adapted)

During such visits the notified body may, if necessary, carry out ~~or have carried out~~ ☒ product ☒ tests ☒ , or have them carried out, in order ☒ to verify that the quality system is functioning correctly. The notified body ~~must~~ ☒ shall ☒ provide the manufacturer with a visit report and, if ~~a test has taken place~~ ☒ tests have been carried out ☒ , with a test report.

↓ new

7. CE marking and EU declaration of conformity

7.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 5.1, the latter's identification number to each individual pressure equipment that satisfies the applicable requirements of this Directive.

7.2. The manufacturer shall draw up a written EU declaration of conformity for each pressure equipment model and keep it at the disposal of the national authorities for 10 years after the pressure equipment has been placed on the market. The EU declaration of conformity shall identify the product model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

↓ 97/23/EC (adapted)

⇒ new

~~68.~~ The manufacturer ~~must~~ ☒ shall ☒ , for a period of ☒ ending ☒ ~~ten~~ 10 years after the ~~last of the~~ pressure equipment has been ~~manufactured~~ ⇒ placed on the market ⇐ , ~~hold~~ ☒ keep ☒ at the disposal of the national authorities:

~~– the technical documentation referred to in section 2,~~

↓ 97/23/EC

– the documentation referred to in ~~the second indent of point 45.1;~~

↓ 97/23/EC (adapted)

⇒ new

– the ~~adjustments~~ ☒ change ☒ referred to in ~~the second paragraph of point 4.45.5;~~

– the decisions and reports ~~from~~ ☒ of ☒ the notified body ~~which are~~ referred to in ~~the last paragraph of points 4.3, the last paragraph of 4.45.5, and in 56.3 and 56.4.~~

~~79.~~ Each notified body ~~must communicate~~ ☒ shall inform ☒ ~~to the Member States the relevant information concerning~~ ⇒ its notifying authorities of ⇐ the quality system approvals ~~which it has~~ ☒ issued or ☒ withdrawn, and ☒ shall ☒ ⇒ periodically ⇐ , ☒ or ☒ ~~on~~ ☒ upon ☒ request, ~~those it has issued~~ ⇒ make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted ⇐ .

Each notified body ~~must also communicate~~ ☒ shall inform ☒ to the other notified bodies ~~the relevant information concerning the~~ ☒ of ☒ quality system approvals ☒ which ☒ it has ☒ refused, suspended, or ☒ withdrawn ~~or refused~~ ⇨ , and upon request, of quality system approvals which it has issued ⇨ .

⇩ new

10. Authorised representative

The manufacturer's obligations set out in points 3, 5.1, 5.5, 7 and 8 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

⇩ 97/23/EC (adapted)

7. MODULE E: ~~(☒ CONFORMITY TO TYPE BASED ON ☒ PRODUCT ☒ PRESSURE EQUIPMENT ☒ QUALITY ASSURANCE)~~

⇩ 97/23/EC

~~1. This module describes the procedure whereby the manufacturer who satisfies the obligations of section 2 ensures and declares that the pressure equipment is in conformity with the type as described in the EC type examination certificate and satisfies the requirements of the Directive which apply to it. The manufacturer, or his authorized representative established within the Community, must affix the CE marking to each product and draw up a written declaration of conformity. The CE marking must be accompanied by the identification number of the notified body responsible for surveillance as specified in section 4.~~

⇩ new

1. Conformity to type based on pressure equipment quality assurance is that part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the pressure equipment concerned is in conformity with the type described in the EU-type examination certificate and satisfies the requirements of this Directive that apply to it.

⇩ 97/23/EC (adapted)

⇨ new

2. ☒ Manufacturing ☒

The manufacturer ~~must~~ ☒ shall ☒ operate an approved quality system for the final ~~pressure equipment~~ ☒ product ☒ inspection and testing ☒ of the pressure equipment concerned ☒ as specified in section point 3 and ☒ shall ☒ be subject to surveillance as specified in section point 4.

3. Quality system

3.1. The manufacturer ~~must~~ ☒ shall ☒ lodge an application for assessment of his quality system ~~for the pressure equipment~~ with a ☒ the ☒ notified body of his choice ☒, for the pressure equipment concerned ☒.

The application ~~must~~ ☒ shall ☒ include:

↓ new

- the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
- a written declaration that the same application has not been lodged with any other notified body;

↓ 97/23/EC (adapted)

- all relevant information on the pressure equipment ☒ type envisaged ☒ ~~concerned;~~
- the documentation concerning the quality system~~;~~
- the technical documentation ~~for~~ ☒ of ☒ the approved type and a copy of the ~~EC type-~~ ☒ EU-type ☒ examination certificate.

3.2. ~~Under the quality system, each item of pressure equipment must be examined and appropriate tests as set out in the relevant standard(s) referred to in Article 5, or equivalent tests, particularly final assessment as referred to in section 3.2 of Annex I, must be carried out in order to ensure its conformity with the requirements of the Directive which apply to it.~~

↓ new

The quality system shall ensure compliance of the products with the type described in the EU-type examination certificate and with the applicable requirements of this Directive.

↓ 97/23/EC (adapted)

All the elements, requirements and provisions adopted by the manufacturer ~~must~~ ☒ shall ☒ be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation ~~must~~ ☒ shall ☒ permit a consistent interpretation of the quality programmes, plans, manuals and records.

It ~~must~~ ☒ shall, in particular, ☒ contain ~~in particular~~ an adequate description of:

- the quality objectives and the ~~organisational~~ structure, responsibilities and powers of the management with regard to ~~the~~ ☒ product ☒ quality ~~of the pressure equipment;~~
- the examinations and tests ~~to~~ ☒ that will ☒ be carried out after manufacture~~;~~

↓ 97/23/EC

- the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications or approvals of the personnel concerned, particularly those of the personnel undertaking the permanent joining of parts and the non-destructive tests in accordance with sections points 3.1.2 and 3.1.3 of Annex I;
 - the means of monitoring the effective operation of the quality system.
-

↓ 97/23/EC (adapted)

⇒ new

3.3. The notified body ~~must~~ ☒ shall ☒ assess the quality system to determine whether it satisfies the requirements referred to in 3.2. ~~The elements of the quality system which conform to the relevant harmonized standard are presumed to comply with the corresponding requirements referred to in 3.2.~~ ⇒ It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the national standard that implements the relevant harmonised standard and/or technical specification. ⇐

☒ In addition to experience in quality management systems, ☒ ~~the~~ the auditing team ~~must~~ ☒ shall ☒ have at least one member with experience of ~~assessing~~ ☒ evaluation in the relevant ☒ the pressure equipment ☒ field and pressure equipment ☒ technology concerned ⇒ and knowledge of the applicable requirements of this Directive ⇐ . The ~~assessment procedure must~~ ☒ audit shall ☒ include an ~~inspection~~ ☒ assessment ☒ visit to the manufacturer's premises.

↓ new

The auditing team shall review the technical documentation referred to in point 3.1, fifth indent, in order to verify the manufacturer's ability to identify the relevant requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the pressure equipment with those requirements.

↓ 97/23/EC (adapted)

The decision ~~must~~ ☒ shall ☒ be notified to the manufacturer. The notification ~~must~~ ☒ shall ☒ contain the conclusions of the ~~examination~~ ☒ audit ☒ and the reasoned assessment decision.

3.4. The manufacturer ~~must~~ ☒ shall ☒ undertake to ~~discharge~~ ☒ fulfil ☒ the obligations arising ~~from~~ ☒ out of ☒ the quality system as approved and to ~~ensure~~ ☒ maintain it so ☒ that it remains ~~satisfactory~~ ☒ adequate ☒ and efficient.

3.5. The manufacturer, ~~or his authorized representative established within the Community,~~ ~~must inform~~ ☒ shall keep ☒ the notified body ~~which~~ ☒ that ☒ has approved the quality system ☒ informed ☒ of any intended ~~adjustment~~ ☒ change ☒ to the quality system.

The notified body ~~must assess~~ ☒ shall evaluate any ☒ the proposed changes and decide whether the modified quality system will ~~still~~ ☒ continue to ☒ satisfy the requirements referred to in point 3.2 or whether a reassessment is ~~required~~ ☒ necessary ☒ .

It ~~must~~ ☒ shall ☒ notify ~~its decision to~~ the manufacturer ☒ of its decision ☒ . The notification ~~must~~ ☒ shall ☒ contain the conclusions of the examination and the reasoned assessment decision.

↓ 97/23/EC

4. Surveillance under the responsibility of the notified body

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

↓ 97/23/EC (adapted)

4.2. The manufacturer ~~must~~ ☒ shall, for assessment purposes, ☒ allow the notified body access ~~for inspection purposes to the locations of~~ ☒ to the manufacture, ☒ inspection, testing and storage ☒ sites ☒ and ☒ shall ☒ provide it with all necessary information, in particular:

↓ 97/23/EC

- the quality system documentation_{2.2};
- the technical documentation_{2.2};
- the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications of the personnel concerned, etc.

↓ 97/23/EC (adapted)

4.3. The notified body ~~must~~ ☒ shall ☒ carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and provide the manufacturer with an audit report. The frequency of periodic audits must be such that a full reassessment is carried out every three years.

↓ 97/23/EC

4.4. In addition the notified body may pay unexpected visits to the manufacturer.

↓ 97/23/EC (adapted)

The need for such additional visits, and the frequency thereof, will be determined on the basis of a visit control system operated by the notified body. In particular, the following factors ~~must~~ ☒ shall ☒ be considered in the visit control system:

- the category of the ☒ pressure ☒ equipment_{2.2};

- the results of previous surveillance visits_{3.3};
- the need to follow up corrective ~~action~~ ☒ actions ☒_{3.3};

↓ 97/23/EC

- special conditions linked to the approval of the system, where applicable_{3.3};
- significant changes in manufacturing organization, policy or techniques.

↓ 97/23/EC (adapted)

During such visits, the notified body may, if necessary, carry out ~~or have carried out~~ ☒ product ☒ tests ☒, or have them carried out, in order ☒ to verify that the quality system is functioning correctly. The notified body ~~must~~ ☒ shall ☒ provide the manufacturer with a visit report and, if ~~a test has taken place~~ ☒ tests have been carried out ☒, with a test report.

↓ new

5. CE marking and EU declaration of conformity

5.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual pressure equipment that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

5.2. The manufacturer shall draw up a written EU declaration of conformity for each pressure equipment model and keep it at the disposal of the national authorities for 10 years after the pressure equipment has been placed on the market. The EU declaration of conformity shall identify the product model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

↓ 97/23/EC (adapted)

⇒ new

~~56.~~ The manufacturer ~~must~~ ☒ shall ☒, for a period of ☒ ending ☒ ~~ten~~ 10 years after the ~~last of the~~ pressure equipment has been ~~manufactured~~ ⇒ placed on the market ⇐, ~~hold~~ ☒ keep ☒ at the disposal of the national authorities:

- the documentation referred to in ~~the second indent of point 3.1~~_{3.1};
- the ~~adjustments~~ ☒ change ☒ referred to in ~~the second paragraph of point 3.45,~~ ☒ as approved, ☒_{3.3};
- the decisions and reports from the notified body which are referred to in ~~the last paragraph of points 3.3, the last paragraph of 3.45, and in 4.3 and 4.4.~~

~~67. Each notified body must~~ ☒ shall ☒ ~~communicate to the Member States the relevant information concerning the~~ ☒ inform its notifying authorities of ☒ quality system approvals which it has ☒ issued or ☒ withdrawn and ☒ shall ☒ ☒ , periodically or ☒ , on ☒ upon ☒ request, ~~those it has issued~~ ☒ make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted ☒ .

Each notified body ~~must~~ ☒ shall ☒ ~~also communicate to~~ ☒ inform ☒ the other notified bodies ~~the relevant information concerning the~~ ☒ of ☒ quality system approvals ☒ which ☒ it has ☒ refused, suspended or ☒ withdrawn ☒ , and, upon request, of quality system approvals which it has issued ☒ or refused.

↓ new

8. Authorised representative

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

↓ 97/23/EC (adapted)

8. MODULE E1: ~~(PRODUCT QUALITY ASSURANCE)~~ ☒ QUALITY ASSURANCE OF FINAL PRESSURE EQUIPMENT INSPECTION AND TESTING ☒

↓ 97/23/EC

~~1. This module describes the procedure whereby the manufacturer who satisfies the obligations of section 3 ensures and declares that the pressure equipment satisfies the requirements of the Directive which apply to it. The manufacturer, or his authorized representative established within the Community, must affix the CE marking to each item of pressure equipment and draw up a written declaration of conformity. The CE marking must be accompanied by the identification number of the notified body responsible for surveillance as specified in section 5.~~

↓ new

1. Quality assurance of final pressure equipment inspection and testing is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 4 and 7, and ensures and declares on his sole responsibility that the pressure equipment concerned satisfy the requirements of this Directive that apply to it.

↓ 97/23/EC (adapted)

☒ new

2. ~~The manufacturer must draw up the~~ Technical documentation described below.

☒ The manufacturer shall establish the technical documentation. ☒ The technical documentation ~~must enable~~ ☒ shall make it possible to ☒ an assessment ~~to be made of~~ the conformity of the pressure equipment with the ☒ relevant ☒ requirements ☒ , and shall

include an adequate analysis and assessment of the risk(s) ~~of the Directive which apply to it. It must~~ ☒ The technical documentation shall specify the applicable requirements and cover ☒ , as far as is relevant for such ☒ the ☒ assessment, ~~cover~~ the design, manufacture and operation of the pressure equipment, ~~and~~ ☒ The technical documentation shall, wherever applicable, ☒ contain ☒ at least the following elements ☒ :

- a general description of the pressure equipment 52;
- conceptual design and manufacturing drawings and ~~diagrams~~ ☒ schemes ☒ of components, sub-assemblies, circuits, etc. 53;
- descriptions and explanations necessary for ~~an~~ ☒ the ☒ understanding of ~~the~~ ☒ those ☒ ~~said~~ drawings and ~~diagrams~~ ☒ schemes ☒ and the operation of the pressure equipment 54;
- a list of the ☒ harmonised ☒ standards ~~referred to in Article 5~~, ☒ the references of which have been published in the *Official Journal of the European Union* ☒, applied in full or in part, and descriptions of the solutions adopted to meet the essential ☒ safety ☒ requirements of ~~the~~ ☒ this ☒ Directive where ~~the~~ ☒ those harmonised ☒ standards ~~referred to in Article 5~~ have not been applied. 55 ☒ In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied; ☒
- results of design calculations made, examinations carried out, etc., ☒ and ☒
- test reports.

↓ new

3. The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the pressure equipment has been placed on the market.

↓ 97/23/EC (adapted)

⇒ new

34. ☒ Manufacturing ☒

The manufacturer ~~must~~ ☒ shall ☒ operate an approved quality system for the final ~~pressure equipment~~ ☒ product ☒ inspection and testing ☒ of the pressure equipment ☒ as specified in section point 45 and ☒ shall ☒ be subject to surveillance as specified in section point 56.

45. Quality system

45.1. The manufacturer ~~must~~ ☒ shall ☒ lodge an application for assessment of his quality system with ~~a~~ ☒ the ☒ notified body of his choice ☒ , for the pressure equipment concerned ☒ .

The application ~~must~~ ☒ shall ☒ include:

↓ new

- the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
 - a written declaration that the same application has not been lodged with any other notified body;
-

↓ 97/23/EC (adapted)
⇒ new

- all relevant information on the pressure equipment ☒ type envisaged ☒ ~~concerned~~ concerned;
- the documentation concerning the quality system ☒ and ☒
- ⇒ the technical documentation referred to in point 2. ⇐

45.2. ⇒ The quality system shall ensure compliance of the pressure equipment with the requirements of this Directive that apply to it. ⇐

Under the quality system, each item of pressure equipment ~~must~~ ☒ shall ☒ be examined and appropriate tests as set out in the relevant standard(s) referred to in Article 512, or equivalent tests, and particularly final assessment as referred to in section point 3.2 of Annex I, ~~must~~ ☒ shall ☒ be carried out in order to ensure its conformity with the requirements of ~~the~~ ☒ this ☒ Directive which apply to it.

All the elements, requirements and provisions adopted by the manufacturer ~~must~~ ☒ shall ☒ be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation ~~must~~ ☒ shall ☒ permit a consistent interpretation of the quality programmes, plans, manuals and records.

It ~~must~~ ☒ shall, in particular, ☒ contain ~~in particular~~ an adequate description of:

↓ 97/23/EC

- the quality objectives and the ~~organisational~~ organisational structure, responsibilities and powers of the management with regard to the quality of the pressure equipment ☒;
 - the procedures used for the permanent joining of parts as approved in accordance with section point 3.1.2 of Annex I ☒;
-

↓ 97/23/EC (adapted)

- the examinations and tests ~~to~~ ☒ that will ☒ be carried out after manufacture ☒;
-

↓ 97/23/EC

- the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications or approvals of the personnel concerned, particularly

those of the personnel undertaking the permanent joining of parts in accordance with section point 3.1.2 of Annex I:

– the means of monitoring the effective operation of the quality system.

↓ 97/23/EC (adapted)

⇒ new

45.3. The notified body ~~must~~ shall assess the quality system to determine whether it satisfies the requirements referred to in 45.2.

⇒ It shall presume conformity with those requirements in respect of the elements of the quality system ~~which conform to the relevant harmonized standard are presumed to~~ that comply with the corresponding requirements referred to in 4.2 specifications of the national standard that implements the relevant harmonised standard and/or technical specification.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of assessing evaluation in the relevant the pressure equipment field and pressure equipment technology concerned, and knowledge of the applicable requirements of this Directive. The assessment procedure must audit shall include an inspection assessment visit to the manufacturer's premises.

↓ new

The auditing team shall review the technical documentation referred to in point 2 in order to verify the manufacturer's ability to identify the relevant requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the pressure equipment with those requirements.

↓ 97/23/EC (adapted)

⇒ new

The decision must shall be notified to the manufacturer. The notification must shall contain the conclusions of the examination audit and the reasoned assessment decision. ~~Provision must be made for an appeals procedure.~~

45.4. The manufacturer must shall undertake to discharge fulfil the obligations arising from out of the quality system as approved and to ensure maintain it so that it remains satisfactory adequate and efficient.

5.5. The manufacturer, ~~or his authorized representative established within the Community,~~ must inform shall keep the notified body which that has approved the quality system informed of any intended adjustment change to the quality system.

The notified body ~~must assess the~~ shall evaluate any proposed changes and decide whether the modified quality system will still continue to satisfy the requirements referred to in point 45.2 or whether a reassessment is required.

It ~~must~~ ☒ shall ☒ notify ☒ the manufacturer of ☒ its decision ~~to the manufacturer~~. The notification ~~must~~ ☒ shall ☒ contain the conclusions of the examination and the reasoned assessment decision.

↓ 97/23/EC

56. Surveillance under the responsibility of the notified body

56.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

↓ 97/23/EC (adapted)

56.2. The manufacturer ~~must~~ ☒ shall, for assessment purposes, ☒ allow the notified body access ~~for inspection purposes~~ to the ~~locations of~~ ☒ manufacture, ☒ inspection, testing and storage ☒ sites ☒ and ☒ shall ☒ provide it with all necessary information, in particular:

- the quality system documentation~~☒~~;
- the technical documentation ☒ referred to in point 2 ☒ ☒;
- the quality records, such as inspection reports and test data, calibration data, ☒ qualification ☒ reports ~~concerning the qualifications of~~ ☒ on ☒ the personnel concerned, etc.

56.3. The notified body ~~must~~ ☒ shall ☒ carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and provide the manufacturer with an audit report. The frequency of periodic audits ~~must~~ ☒ shall ☒ be such that a full reassessment is carried out every three years.

56.4. In addition the notified body may pay unexpected visits to the manufacturer. The need for such additional visits, and the frequency thereof, will be determined on the basis of a visit control system operated by the notified body. In particular, the following factors ~~must~~ ☒ shall ☒ be considered in the visit control system:

↓ 97/23/EC

- the category of the equipment ,
 - the results of previous surveillance visits~~☒~~;
 - the need to follow up corrective action~~(s)~~~~☒~~;
 - special conditions linked to the approval of the system, where applicable~~☒~~;
 - significant changes in manufacturing organizization, policy or techniques.
-

↓ 97/23/EC (adapted)

During such visits the notified body may, if necessary, carry out ~~or have carried out~~ ☒ product ☒ tests, ☒ or have them carried out, in order ☒ to verify that the quality

system is functioning correctly. The notified body ~~must~~ ☒ shall ☒ provide the manufacturer with a visit report and, if ~~a test has taken place~~ ☒ tests have been carried out ☒ , with a test report.

↓ new

7. CE marking and EU declaration of conformity

7.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 5.1, the latter's identification number to each individual pressure equipment that satisfies the applicable requirements of this Directive.

7.2. The manufacturer shall draw up a written EU declaration of conformity for each pressure equipment model and keep it at the disposal of the national authorities for 10 years after the pressure equipment has been placed on the market. The EU declaration of conformity shall identify the pressure equipment model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

↓ 97/23/EC (adapted)

⇒ new

~~68.~~ The manufacturer ~~must~~ ☒ shall ☒ , for a period of ☒ ending ☒ ~~ten~~ 10 years after the ~~last of the~~ pressure equipment has been ~~manufactured~~ ☒ placed on the market ☒ , keep at the disposal of the national authorities:

- ~~the technical documentation referred to in section 2,~~
- the documentation referred to in ~~the second indent of point 45.1;~~
- the ~~adjustments~~ ☒ change ☒ referred to in ~~the second paragraph of point 4.4~~ 5.5, ☒ as approved; ☒
- the decisions and reports ~~from~~ ☒ of ☒ the notified body ~~which are~~ referred to in ~~the last paragraph of 45.3, the last paragraph of 4.45.5, and in 56.3 and 56.4.~~

~~79.~~ Each notified body ~~must communicate~~ ☒ shall inform ☒ ~~to the Member States the relevant information concerning the~~ ☒ its notifying authorities of ☒ quality system approvals ~~which it has~~ ☒ issued or ☒ withdrawn and ☒ shall ☒ ☒ periodically or ☒ , ~~on~~ ☒ upon ☒ request, ~~those is has issued~~ ☒ make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted ☒ .

Each notified body ~~must also communicate~~ ☒ shall inform ☒ the other notified bodies ~~the relevant information concerning the~~ ☒ of ☒ quality system approvals ☒ which ☒ it has ☒ refused, suspended or ☒ withdrawn ☒ , and, upon request, of quality system approvals which it has issued ☒ ~~or refused.~~

↓ new

10. Authorised representative

The manufacturer's obligations set out in points 3, 5.1, 5.5, 7 and 8 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

↓ 97/23/EC (adapted)
⇒ new

9. MODULE F: ~~€~~ ☒ CONFORMITY TO TYPE BASED ON ☒ ~~PRODUCT~~ ☒ PRESSURE EQUIPMENT ☒ VERIFICATION

1. ~~This module describes the~~ ☒ Conformity to type based on pressure equipment verification is the part of a conformity assessment ☒ procedure whereby ~~a~~ ☒ the ☒ manufacturer, ~~or his authorized representative established within the Community,~~ ☒ fulfils the obligations laid down in points 2 and 5, and ☒ ensures and declares ☒ on his sole responsibility ☒ that the pressure equipment ☒ concerned, which has been ☒ subject to the provisions of section point 3, is in conformity with the type described in the EC type- ☒ EU-type ☒ examination certificate, ~~or~~

~~in the EC design examination certificate~~

and satisfies the requirements of ~~the~~ ☒ this ☒ Directive which apply to it.

2. ☒ Manufacturing ☒

The manufacturer ~~must~~ ☒ shall ☒ take all measures necessary ~~to ensure~~ ☒ so ☒ that the manufacturing process ☒ and its monitoring ensure conformity of the manufactured products ☒ ~~requires the pressure equipment to comply with the~~ ☒ approved ☒ type described in the ~~EC type-~~ ☒ EU-type ☒ examination certificate, ~~or~~

~~in the EC design examination certificate~~

and with the requirements of ~~the~~ ☒ this ☒ Directive which apply to ~~it~~ ☒ them ☒.

~~The manufacturer, or his authorized representative established within the Community, must affix the CE marking to all pressure equipment and draw up a declaration of conformity.~~

3. ☒ Verification ☒

~~The~~ ☒ A ☒ notified body ☒ chosen by the manufacturer ☒ ~~must perform~~ ☒ shall carry out ☒ the appropriate examinations and tests in order to check the conformity of the pressure equipment with the ~~relevant~~ ☒ approved type described in the EU-type examination certificate and with the appropriate ☒ requirements of ~~the~~ ☒ this ☒ Directive ~~by examining and testing every product in accordance with section 4.~~

↓ 97/23/EC

~~The manufacturer, or his authorized representative established within the Community, must keep a copy of the declaration of conformity for a period of ten years after the last of the pressure equipment has been manufactured.~~

↓ new

The examinations and tests to check the conformity of the pressure equipment with the appropriate requirements shall be carried out by examination and testing of every product as specified in point 4.

↓ 97/23/EC (adapted)
⇒ new

4. Verification ☒ of conformity ☒ by examination and testing of ~~each item of~~ ☒ every ☒ pressure equipment

4.1. ~~Each item of~~ ☒ All ☒ pressure equipment ~~must~~ ☒ shall ☒ be individually examined and ~~must undergo appropriate examinations and tests as set out in the relevant~~ ☒ harmonised ☒ standard(s) ~~referred to in Article 5 or equivalent examinations and tests~~ ☒ shall be carried out ☒ in order to verify ~~that it conforms to the~~ ☒ conformity with the approved ☒ type and ⇒ described in the EU-type examination certificate and with the appropriate ⇐ ~~the requirements of the~~ ☒ this ☒ Directive ~~which apply to it.~~ ⇒ In the absence of such a harmonised standard, the notified body concerned shall decide on the appropriate tests to be carried out. ⇐

In particular, the notified body ~~must~~ ☒ shall ☒:

↓ 97/23/EC

- verify that the personnel undertaking the permanent joining of parts and the non-destructive tests are qualified or approved in accordance with sections points 3.1.2 and 3.1.3 of Annex I₂;
 - verify the certificate issued by the materials manufacturer in accordance with section point 4.3 of Annex I₂;
 - carry out or have carried out the final inspection and proof test referred to in section point 3.2 of Annex I and examine the safety devices, if applicable.
-

↓ 97/23/EC (adapted)
⇒ new

4.2. The notified body ~~must~~ ☒ shall ☒ ⇒ issue a certificate of conformity in respect of the examinations and tests carried out, and ⇐ ☒ shall ☒ affix its identification number or have it affixed ⇒ under its responsibility ⇐ ~~to each item of~~ ☒ approved ☒ pressure equipment ~~and draw up a written certificate of conformity relating to the tests carried out.~~

↓ new

The manufacturer shall keep the certificates of conformity available for inspection by the national authorities for 10 years after the pressure equipment has been placed on the market.

↓ 97/23/EC

~~4.3. The manufacturer, or his authorized representative established within the Community, must ensure that the certificates of conformity issued by the notified body can be made available on request.~~

↓ new

5. CE marking and EU declaration of conformity

5.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 3, the latter's identification number to each individual pressure equipment that is in conformity with the approved type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

5.2. The manufacturer shall draw up a written EU declaration of conformity for each pressure equipment model and keep it at the disposal of the national authorities, for 10 years after the pressure equipment has been placed on the market. The EU declaration of conformity shall identify the pressure equipment model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

If the notified body referred to in point 3 agrees and under its responsibility, the manufacturer may also affix the notified body's identification number to the pressure equipment.

6. If the notified body agrees and under its responsibility, the manufacturer may affix the notified body's identification number to the pressure equipment during the manufacturing process.

7. Authorised representative

The manufacturer's obligations may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate. An authorised representative may not fulfil the manufacturer's obligations set out in points 2.

↓ 97/23/EC (adapted)

10. MODULE G:

~~☒~~ ☒ CONFORMITY BASED ON ~~☒~~ ☒ ~~EC~~ UNIT VERIFICATION~~☒~~

↓ 97/23/EC

~~1. This module describes the procedure whereby the manufacturer ensures and declares that pressure equipment which has been issued with the certificate referred to in section 4.1 satisfies the requirements of the Directive which apply to it. The manufacturer must affix the CE marking to the pressure equipment and draw up a declaration of conformity.~~

↓ new

1. Conformity based on unit verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 5, and ensures and declares on his sole responsibility that the pressure equipment concerned, which has been subject to the provisions of point 4, is in conformity with the requirements of this Directive that apply to it.

↓ 97/23/EC

~~2. The manufacturer must apply to a notified body of his choice for unit verification.~~

~~The application must contain:~~

~~the name and address of the manufacturer and the location of the pressure equipment,~~

~~a written declaration to the effect that a similar application has not been lodged with another notified body,~~

~~technical documentation.~~

↓ 97/23/EC (adapted)

32. ☒ Technical documentation ☒

↓ new

The manufacturer shall establish the technical documentation and make it available to the notified body referred to in point 4.

↓ 97/23/EC (adapted)

⇒ new

The ~~technical~~ documentation ~~must enable~~ ☒ shall make it possible to assess ☒ the conformity of the pressure equipment with the ☒ relevant ☒ requirements ~~of the Directive which apply to it to be assessed~~ and ⇒ shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, ⇐ the design, manufacture and operation of the pressure equipment ~~to be understood~~.

The technical documentation ~~must~~ ☒ shall, wherever applicable, ☒ contain ☒ at least the following elements ☒ :

↓ 97/23/EC

– a general description of the pressure equipment;

↓ 97/23/EC (adapted)

⇒ new

- conceptual design and manufacturing drawings and ~~diagrams~~ ☒ schemes ☒ of components, sub-assemblies, circuits, etc._{5.2}
- descriptions and explanations necessary for an understanding of ~~the~~ ☒ those ☒ ~~said~~ drawings and ~~diagrams~~ ☒ schemes ☒ and the operation of the pressure equipment_{5.2}
- a list of the ☒ harmonised ☒ standards ~~referred to in Article 5~~ ☒ the references of which have been published in the *Official Journal of the European Union* ☒, applied in full or in part, and descriptions of the solutions adopted to meet the essential ☒ safety ☒ requirements of ~~the~~ ☒ this ☒ Directive where ~~the~~ ☒ those harmonised ☒ standards, ~~referred to in Article 5~~ have not been applied_{5.2} ⇒ In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied; ⇐
- results of design calculations made, examinations carried out, etc._{5.2}

↓ 97/23/EC

- test reports_{5.2}
- appropriate details relating to the approval of the manufacturing and test procedures and of the qualifications or approvals of the personnel concerned in accordance with sections points 3.1.2 and 3.1.3 of Annex I.

↓ new

The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the pressure equipment has been placed on the market.

3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured pressure equipment with the applicable requirements of this Directive.

↓ 97/23/EC (adapted)

⇒ new

4. ☒ Verification ☒

~~The~~ ☒ A ☒ notified body ☒ chosen by the manufacturer ☒ ~~must~~ ☒ shall carry out appropriate examinations ☒ ~~examine the design and construction of each item of pressure equipment and during manufacture perform appropriate~~ ☒ and ☒ tests, as set out in the relevant ☒ harmonised ☒ standard(s) ~~referred to in Article 5 of the Directive~~, and/or equivalent ~~examinations and~~ tests, to ensure its ☒ check the ☒ conformity ☒ of the pressure equipment ☒ with the ☒ applicable ☒ requirements of ~~the~~ ☒ this ☒ Directive

~~which apply to it,~~ ⇒ or have them carried out. In the absence of such a harmonised standard the notified body concerned shall decide on the appropriate tests to be carried out applying other technical specifications. ⇐

In particular the notified body ~~must~~ ☒ shall ☒:

↓ 97/23/EC

- examine the technical documentation with respect to the design and the manufacturing procedures;
- assess the materials used where these are not in conformity with the relevant harmonised standards or with a European approval for pressure equipment materials, and check the certificate issued by the material manufacturer in accordance with section point 4.3 of Annex I;
- approve the procedures for the permanent joining of parts or check that they have been previously approved in accordance with section point 3.1.2 of Annex I;
- verify the qualifications or approvals required under sections points 3.1.2 and 3.1.3 of Annex I;
- carry out the final inspection referred to in section point 3.2.1 of Annex I, perform or have performed the proof test referred to in section point 3.2.2 of Annex I, and examine the safety devices, if applicable.

↓ 97/23/EC (adapted)

⇒ new

~~4.1. The notified body must ☒ shall ☒ ⇒ issue a certificate of conformity in respect of the examinations and tests carried out and ⇐ ☒ shall ☒ affix its identification number ☒ to the approved pressure equipment, ☒ or have it affixed to the pressure equipment and draw up a certificate of conformity for the tests carried out ☒ under its responsibility ☒ . This ☒ The ☒ certificate must be kept for a period of ⇒ manufacturer shall keep the certificates of conformity at the disposal of the national authorities for ⇐ ten 10 years ⇒ after the pressure equipment has been placed on the market ⇐ .~~

↓ 97/23/EC

~~4.2. The manufacturer, or his authorized representative established within the Community, must ensure that the declaration of conformity and certificate of conformity issued by the notified body can be made available on request.~~

↓ new

5. CE marking and EU declaration of conformity

5.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 4, the latter's identification number to each pressure equipment that satisfies the applicable requirements of this Directive.

5.2. The manufacturer shall draw up a written EU declaration of conformity and keep it at the disposal of the national authorities for 10 years after the pressure equipment has been placed on the market. The EU declaration of conformity shall identify the pressure equipment for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

6. Authorised representative

The manufacturer's obligations set out in points 2 and 5 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

↓ 97/23/EC (adapted)

11. MODULE H: ☒ CONFORMITY BASED ON ☒ FULL QUALITY ASSURANCE

↓ 97/23/EC

~~1. This module describes the procedure whereby the manufacturer who satisfies the obligations of section 2 ensures and declares that the pressure equipment in question satisfies the requirements of the Directive which apply to it. The manufacturer, or his authorized representative established within the Community, must affix the CE marking to each item of pressure equipment and draw up a written declaration of conformity. The CE marking must be accompanied by the identification number of the notified body responsible for surveillance as specified in section 4.~~

↓ new

1. Conformity based on full quality assurance is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the pressure equipment concerned satisfies the requirements of this Directive that apply to it.

↓ 97/23/EC (adapted)

2. ☒ Manufacturing ☒

The manufacturer ~~must implement~~ ☒ shall operate ☒ an approved quality system for design, manufacture, final ☒ product ☒ inspection and testing ☒ of the pressure equipment ☒ as specified in ~~section~~ point 3 and ☒ shall ☒ be subject to surveillance as specified in ~~section~~ point 4.

3. Quality system

3.1. The manufacturer ~~must~~ ☒ shall ☒ lodge an application for assessment of his quality system with ~~a~~ ☒ the ☒ notified body of his choice, ☒ for the pressure equipment concerned ☒.

The application ~~must~~ ☒ shall ☒ include:

↓ 97/23/EC

- ~~all relevant information concerning the pressure equipment in question;~~

↓ new

- the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
- the technical documentation for one model of each type of pressure equipment intended to be manufactured. The technical documentation shall, wherever applicable, contain at least the following elements:
 - a general description of the pressure equipment;
 - conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;
 - descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the pressure equipment;
 - a list of the harmonised standards the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;
 - results of design calculations made, examinations carried out, etc.;
 - test reports;

↓ 97/23/EC (adapted)

- the documentation concerning the quality system ☒ and ☒

↓ new

- a written declaration that the same application has not been lodged with any other notified body.

↓ 97/23/EC (adapted)

3.2. The quality system ~~must~~ ☒ shall ☒ ensure compliance of the pressure equipment with the requirements of ~~the~~ ☒ this ☒ Directive ~~which~~ ☒ that ☒ apply to it.

All the elements, requirements and provisions adopted by the manufacturer ~~must~~ ☒ shall ☒ be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. ~~This~~ ☒ That ☒ quality system documentation ~~must~~ ☒ shall ☒ permit a

consistent interpretation of the ~~procedural and quality measures such as~~ programmes, plans, manuals and records.

It ~~must~~ ☒ shall ☒ ~~contain~~ ☒, in particular, ☒ contain ☒ an adequate description of:

- the quality objectives and the ~~organisational~~ structure, responsibilities and powers of the management with regard to ~~the quality of the design and to~~ product quality;
- the technical design specifications, including standards, that will be applied and, where the ☒ relevant harmonised ☒ standards ~~referred to in Article 5 are~~ ☒ will ☒ not ☒ be ☒ applied in full, the means that will be used to ensure that the essential requirements of ~~the~~ ☒ this ☒ Directive ~~which~~ ☒ that ☒ apply to the pressure equipment will be met;

↓ 97/23/EC (adapted)

⇒ new

- the design control and design verification techniques, processes and systematic ~~measures~~ ☒ actions ☒ that will be used when designing the pressure equipment, ~~⇒ pertaining to the product type covered,~~ ☒ particularly with regard to materials in accordance with section point 4 of Annex I;
- the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic ~~measures~~ ☒ actions ☒ that will be used, particularly the procedures for the permanent joining of parts as approved in accordance with section point 3.1.2 of Annex I;

↓ 97/23/EC

- the examinations and tests to be carried out before, during, and after manufacture, and the frequency with which they will be carried out;

↓ 97/23/EC (adapted)

⇒ new

- the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications or approvals of the personnel concerned, particularly those of the personnel undertaking the permanent joining of parts and the non-destructive tests in accordance with sections points 3.1.2 and 3.1.3 of Annex I, ☒ etc.; ☒
- the means of monitoring the achievement of the required ☒ design and ☒ pressure equipment ~~design and~~ quality and the effective operation of the quality system.

3.3. The notified body ~~must~~ ☒ shall ☒ assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. ~~The elements of the quality system which conform to the relevant harmonized standard are presumed to comply with the corresponding requirements referred to in 3.2.~~ ☒ It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the national standard that implements the relevant harmonised standard and/or technical specification. ☒

☒ In addition to experience in quality management systems, ☒ ~~the~~ auditing team ~~must~~ ☒ shall ☒ have at least one member ~~with experience of~~ ☒ experienced as assessor ☒ ~~assessing~~ ☒ in ☒ the pressure equipment technology concerned ☒, and knowledge of the applicable requirements of this Directive ☒. The ~~assessment procedure must~~ ☒ audit shall ☒ include an ~~inspection~~ ☒ assessment ☒ visit to the manufacturer's premises.

↓ new

The auditing team shall review the technical documentation referred to in point 3.1, second indent, to verify the manufacturer's ability to identify the applicable requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the pressure equipment with those requirements.

↓ 97/23/EC (adapted)

The ☒ manufacturer or his authorised representative ☒ ~~decision must~~ ☒ shall ☒ be notified ☒ of the decision ☒ ~~to the manufacturer~~. The notification ~~must~~ ☒ shall ☒ contain the conclusions of the ~~examination~~ ☒ audit ☒ and the reasoned assessment decision. ~~Provision must be made for an appeals procedure.~~

3.4. The manufacturer ~~must~~ ☒ shall ☒ undertake to fulfil the obligations arising out of the quality system as approved and to ~~ensure~~ ☒ maintain it so ☒ that it remains ~~satisfactory~~ ☒ adequate ☒ and efficient.

The manufacturer, ~~or his authorized representative established within the Community, must inform~~ ☒ shall keep ☒ the notified body that has approved the quality system ☒ informed ☒ of any intended ~~adjustment~~ ☒ change ☒ to the quality system.

The notified body ~~must assess~~ ☒ shall evaluate ☒ ~~the~~ ☒ any ☒ proposed changes and decide whether the modified quality system will ~~still~~ ☒ continue to ☒ satisfy the requirements referred to in 3.2 or whether a reassessment is ~~required~~ ☒ necessary ☒.

It ~~must~~ ☒ shall ☒ notify ~~its decision to~~ the manufacturer ☒ of its decision ☒. The notification ~~must~~ ☒ shall ☒ contain the conclusions of the examination and the reasoned assessment decision.

4. Surveillance under the responsibility of the notified body

4.1. The purpose of ~~this~~ surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2. The manufacturer ~~must~~ ☒ shall, for assessment purposes, ☒ allow the notified body access ~~for inspection purposes to the locations of~~ design, manufacture, inspection, testing and storage ☒ sites ☒ and ☒ shall ☒ provide it with all necessary information, in particular:

- the quality system documentation;⁵²
- the quality records provided for ~~in~~ ☒ by ☒ the design part of the quality system, such as results of analyses, calculations, tests, etc.⁵³

- the quality records provided for ~~in~~ ☐ by ☐ the manufacturing part of the quality system, such as inspection reports and test data, calibration data, ☐ qualification ☐ reports ~~concerning the qualifications of~~ ☐ on ☐ the personnel concerned, etc.

4.3. The notified body ~~must~~ ☐ shall ☐ carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and ☐ shall ☐ provide the manufacturer with an audit report. The frequency of periodic audits ~~must~~ ☐ shall ☐ be such that a full reassessment is carried out every three years.

4.4. In addition, the notified body may pay unexpected visits to the manufacturer.

The need for such additional visits, and the frequency thereof, will be determined on the basis of a visit control system operated by the notified body. In particular, the following factors ~~must~~ ☐ shall ☐ be considered in the visit control system:

↓ 97/23/EC

- the category of the equipment₂;
- the results of previous surveillance visits₂;
- the need to follow up corrective action(s)₂;
- special conditions linked to the approval of the system, where applicable₂;
- significant changes in manufacturing organization, policy or techniques.

↓ 97/23/EC (adapted)

⇒ new

During such visits, the notified body may, if necessary, carry out ~~or have carried out~~ ☐ product ☐ tests ☐ , or have them carried out, in order ☐ to ~~verify that the quality system is~~ ☐ check the proper ☐ functioning ~~correctly~~ ☐ of the quality system ☐ . ~~The notified body~~ ☐ It ☐ ~~must~~ ☐ shall ☐ provide the manufacturer with a visit report and, if a ~~test has taken place~~ ☐ tests have been carried out ☐ , with a test report.

↓ new

5. CE marking and EU declaration of conformity

5.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual pressure equipment that satisfies the applicable requirements of this Directive.

5.2. The manufacturer shall draw up a written EU declaration of conformity for each pressure equipment model and keep it at the disposal of the national authorities for 10 years after the pressure equipment has been placed on the market. The EU declaration of conformity shall identify the pressure equipment model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

↓ 97/23/EC (adapted)

⇒ new

56. The manufacturer ~~must~~ ☒ shall ☒, for a period of ☒ ending ☒ ~~ten~~ 10 years after the last of the pressure equipment has been ~~manufactured~~ ⇒ placed on the market ⇐, keep at the disposal of the national authorities:

- the ☒ technical ☒ documentation referred to in ~~the second indent of the second subparagraph of point 3.1;~~
- ⇒ the documentation concerning the quality system referred to in point 3.1; ⇐
- the ~~adjustments~~ ☒ change ☒ referred to ~~in the second subparagraph of point 3.4,~~ ☒ as approved ☒ ;
- the decisions and reports ~~from~~ ☒ of ☒ the notified body ~~which are~~ referred to in ~~the last subparagraph of point 3.3, the last subparagraph of 3.4, and in 4.3 and 4.4.~~

67. Each notified body ~~must communicate to the Member States~~ ⇒ shall inform its notifying authorities of ⇐ ~~the relevant information concerning the quality system approvals which it has~~ ☒ issued or ☒ withdrawn, and ⇒ shall, periodically or ⇐ ; ~~on~~ ☒ upon ☒ request, ~~those it has issued~~ ⇒ make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted ⇐ .

Each notified body ~~must also communicate to~~ ☒ shall inform ☒ the other notified bodies ~~the relevant information concerning the~~ ☒ of ☒ quality system approvals ☒ which ☒ it has ☒ refused, suspended or ☒ withdrawn, ~~or refused~~ ⇒ and, upon request, of quality system approvals which it has issued ⇐ .

↓ new

8. Authorised representative

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

↓ 97/23/EC (adapted)

12. MODULE H1: ~~☒ CONFORMITY BASED ON ☒ FULL QUALITY ASSURANCE WITH ☒ PLUS ☒ DESIGN EXAMINATION AND SPECIAL SURVEILLANCE OF THE FINAL ASSESSMENT~~

↓ 97/23/EC

1. In addition to the requirements of module H, the following apply:

- (a) ~~the manufacturer must lodge an application for examination of the design with the notified body;~~

~~(b) — the application must enable the design, manufacture and operation of the pressure equipment to be understood, and enable conformity with the relevant requirements of the Directive to be assessed.~~

~~It must include:~~

~~— the technical design specifications, including standards, which have been applied;~~

~~— the necessary supporting evidence for their adequacy, in particular where the standards referred to in Article 5 have not been applied in full. This supporting evidence must include the results of tests carried out by the appropriate laboratory of the manufacturer or on his behalf;~~

~~(c) — the notified body must examine the application and where the design meets the provisions of the Directive which apply to it issue an EC design examination certificate to the applicant. The certificate must contain the conclusions of the examination, the conditions for its validity, the necessary data for identification of the approved design and, if relevant, a description of the functioning of the pressure equipment or accessories;~~

~~(d) — the applicant must inform the notified body that has issued the EC design examination certificate of all modifications to the approved design. Modifications to the approved design must receive additional approval from the notified body that issued the EC design examination certificate where they may affect conformity with the essential requirements of the Directive or the prescribed conditions for use of the pressure equipment. This additional approval must be given in the form of an addition to the original EC design examination certificate;~~

~~(e) — each notified body must also communicate to the other notified bodies the relevant information concerning the EC design examination certificates it has withdrawn or refused.~~

~~2. Final assessment as referred to in section 3.2 of Annex I is subject to increased surveillance in the form of unexpected visits by the notified body. In the course of such visits, the notified body must conduct examinations on the pressure equipment.~~

↓ new

1. Conformity based on full quality assurance plus design examination and special surveillance of the final assessment is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 6, and ensures and declares on his sole responsibility that the pressure equipment concerned satisfy the requirements of the Directive that apply to it.

2. Manufacturing

The manufacturer shall operate an approved quality system for design, manufacture and final product inspection and testing of the products concerned as specified in point 3 and shall be subject to surveillance as specified in point 5. The adequacy of the technical design of the pressure equipment shall have been examined in accordance with point 4.

3. Quality system

3.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the pressure equipment concerned.

The application shall include:

- the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
- the technical documentation for one model of each type of pressure equipment intended to be manufactured. The technical documentation shall, wherever applicable, contain at least the following elements:
 - a general description of the pressure equipment;
 - conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,
 - descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the pressure equipment;
 - a list of the harmonised standards the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;
 - results of design calculations made, examinations carried out, etc.;
 - test reports;
- the documentation concerning the quality system;
- a written declaration that the same application has not been lodged with any other notified body.

3.2. The quality system shall ensure compliance of the pressure equipment with the requirements of this Directive that apply to it.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality;
- the technical design specifications, including standards, that will be applied and, where relevant harmonised standards will not be applied in full, the means that will

be used to ensure that the essential safety requirements of the Directive that apply to the pressure equipment will be met;

- the design control and design verification techniques, processes and systematic actions that will be used when designing the pressure equipment pertaining to the pressure equipment type covered, particularly with regard to materials in accordance with point 4 of Annex I;
- the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used, particularly the procedures for the permanent joining of parts as approved in accordance with point 3.1.2 of Annex I;
- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;
- the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications or approvals of the personnel concerned, particularly those of the personnel undertaking the permanent joining of parts and the non-destructive tests in accordance with points 3.1.2 and 3.1.3 of Annex I, etc.;
- the means of monitoring the achievement of the required design and pressure equipment quality and the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the national standard that implements the relevant harmonised standard and/or technical specifications. In addition to experience in quality management systems, the auditing team shall have at least one member experienced as an assessor in the relevant pressure equipment field and pressure equipment technology concerned, and knowledge of the applicable requirements of this Directive. The audit shall include an assessment visit to the manufacturer's premises.

The auditing team shall review the technical documentation referred to in point 3.1, second indent, to verify the manufacturer's ability to identify the applicable requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the pressure equipment with those requirements.

The manufacturer or his authorised representative shall be notified of the decision.

The notification shall contain the conclusions of the audit and the reasoned assessment decision.

3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a re-assessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

3.6. Each notified body shall inform its notifying authorities of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.

4. Design examination

4.1. The manufacturer shall lodge an application for examination of the design of each item of pressure equipment not covered by a previous design examination with the notified body referred to in point 3.1.

4.2. The application shall make it possible to understand the design, manufacture and operation of the pressure equipment, and to assess the conformity with the requirements of this Directive that apply to it. It shall include:

- the name and address of the manufacturer;
- a written declaration that the same application has not been lodged with any other notified body;
- the technical documentation. The documentation shall make it possible to assess the conformity of the pressure equipment with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design and operation of the pressure equipment. The technical documentation shall, wherever applicable, contain at least the following elements:
 - a general description of the pressure equipment;
 - conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;
 - descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the pressure equipment;
 - a list of the harmonised standards the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive, where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;

- results of design calculations made, examinations carried out, etc., and
- test reports;
- the supporting evidence for the adequacy of the technical design. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards have not been applied in full, and shall include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer or by another testing laboratory on his behalf and under his responsibility.

4.3. The notified body shall examine the application, and where the design meets the requirements of this Directive that apply to the pressure equipment it shall issue an EU design examination certificate to the manufacturer. The certificate shall give the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the data necessary for identification of the approved design. The certificate may have one or more annexes attached.

The certificate and its annexes shall contain all relevant information to allow the conformity of manufactured products with the examined design to be evaluated, and to allow for in-service control, where applicable.

Where the design does not satisfy the applicable requirements of this Directive, the notified body shall refuse to issue a design examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

4.4. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved design may no longer comply with the applicable requirements of this Directive, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

The manufacturer shall keep the notified body that has issued the EU design examination certificate informed of any modification to the approved design that may affect the conformity with the essential safety requirements of this Directive or the conditions for validity of the certificate. Such modifications shall require additional approval - from the notified body that issued the EU design examination certificate - in the form of an addition to the original EU design examination certificate.

4.5. Each notified body shall inform its notifying authorities of the EU design examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of the EU design examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, of the certificates and/or additions thereto which it has issued.

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU design examination certificates and/or additions thereto. On request, the

Commission and the Member States may obtain a copy of the technical documentation and of the results of the examinations carried out by the notified body.

The notified body shall keep a copy of the EU design examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer until the expiry of the validity of the certificate.

4.6. The manufacturer shall keep a copy of the EU design examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the pressure equipment has been placed on the market.

5. Surveillance under the responsibility of the notified body

5.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

5.2. The manufacturer shall, for assessment purposes, allow the notified body access to the design, manufacture, inspection, testing and storage sites, and shall provide it with all necessary information, in particular:

- the quality system documentation;
- the quality records as provided for by the design part of the quality system, such as results of analyses, calculations, tests, etc.;
- the quality records as provided for by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

5.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report. The frequency of periodic audits shall be such that a full reassessment is carried out every three years.

5.4. In addition, the notified body may pay unexpected visits to the manufacturer.

The need for such additional visits, and the frequency thereof, will be determined on the basis of a visit control system operated by the notified body. In particular, the following factors must be considered in the visit control system:

- the category of the equipment;
- the results of previous surveillance visits;
- the need to follow up corrective action(s);
- special conditions linked to the approval of the system, where applicable;
- significant changes in manufacturing organisation, policy or techniques.

During such visits, the notified body may, if necessary, carry out product tests, or have them carried out, in order to check the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

5.5 Special surveillance of the final assessment

Final assessment as referred to in section 3.2 of Annex I is subject to increased surveillance in the form of unexpected visits by the notified body. In the course of such visits, the notified body shall conduct examinations on the pressure equipment.

It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

6. CE marking and EU declaration of conformity

6.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual pressure equipment that satisfies the applicable requirements of this Directive.

6.2. The manufacturer shall draw up a written EU declaration of conformity for each pressure equipment model and keep it at the disposal of the national authorities for 10 years after the pressure equipment has been placed on the market. The EU declaration of conformity shall identify the pressure equipment model for which it has been drawn up and shall mention the number of the design examination certificate.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

7. The manufacturer shall, for a period ending 10 years after the pressure equipment has been placed on the market, keep at the disposal of the national authorities:

- the documentation concerning the quality system referred to in point 3.1;
- the change referred to in point 3.5, as approved;
- the decisions and reports of the notified body referred to in points 3.5, 5.3 and 5.4.

8. Authorised representative

The manufacturer's authorised representative may lodge the application referred to in points 4.1 and 4.2 and fulfil the obligations set out in points 3.1, 3.5, 4.4, 4.6, 6 and 7, on his behalf and under his responsibility, provided that they are specified in the mandate.

↓ 97/23/EC

ANNEX IV

MINIMUM CRITERIA TO BE MET WHEN DESIGNATING THE NOTIFIED BODIES REFERRED TO IN ARTICLE 12 AND THE RECOGNIZED THIRD-PARTY ORGANIZATIONS REFERRED TO IN ARTICLE 13

~~1. The body, its director and the personnel responsible for carrying out the assessment and verification operations may not be the designer, manufacturer, supplier, installer or user of the pressure equipment or assemblies which that body inspects, nor the authorized representative of any of those parties. They may not become directly involved in the design, construction, marketing or maintenance of the pressure equipment or assemblies, nor represent the parties~~

engaged in these activities. This does not preclude the possibility of exchanges of technical information between the manufacturer of pressure equipment or assemblies and the notified body.

2. The body and its personnel must carry out the assessments and verifications with the highest degree of professional integrity and technical competence and must be free from all pressures and inducements, particularly financial, which might influence their judgment or the results of the inspection, especially from persons or groups of persons with an interest in the results of verifications.

3. The body must have at its disposal the necessary personnel and possess the necessary facilities to enable it to perform properly the technical and administrative tasks connected with the inspection and surveillance operations, it must also have access to the equipment required to perform special verifications.

4. The personnel responsible for inspection must have:

— sound technical and vocational training,

— satisfactory knowledge of the requirements of the inspections they carry out and adequate experience of such operations,

— the ability required to draw up the certificates, records and reports to demonstrate that the inspections have been carried out.

5. The impartiality of the inspection personnel must be guaranteed. Their remuneration must not depend on the number of inspections carried out, nor on the results of such inspections.

6. The body must take out liability insurance unless its liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the inspections.

7. The personnel of the body must observe professional secrecy with regard to all information gained in carrying out their tasks (except vis-à-vis the competent administrative authorities of the State in which their activities are carried out) under the Directive or any provision of national law giving effect to it.

ANNEX V

CRITERIA TO BE MET WHEN AUTHORIZING USER INSPECTORATES REFERRED TO IN ARTICLE 14

1. The user inspectorate must be organizationally identifiable and have reporting methods within the group of which it is part which ensure and demonstrate its impartiality. It must not be responsible for the design, manufacture, supply, installation, operation or maintenance of the pressure equipment or assemblies, and must not engage in any activities that might conflict with its independence of judgment and integrity in relation to its inspection activities.

2. The user inspectorate and its personnel must carry out the assessments and verifications with the highest degree of professional integrity and technical competence and must be free from all pressures and inducements, particularly financial, which might influence their

judgment or the results of the inspection, especially from persons or groups of persons with an interest in the results of verifications.

3. The user inspectorate must have at its disposal the necessary personnel and possess the necessary facilities to enable it to perform properly the technical and administrative tasks connected with the inspection and surveillance operations; it must also have access to the equipment required to perform special verifications.

4. The personnel responsible for inspection must have:

— sound technical and vocational training,

— satisfactory knowledge of the requirements of the inspections they carry out and adequate experience of such operations,

— the ability required to draw up the certificates, records and reports to demonstrate that the inspections have been carried out.

5. The impartiality of inspection personnel must be guaranteed. Their remuneration must not depend on the number of inspections carried out, nor on the results of such inspections.

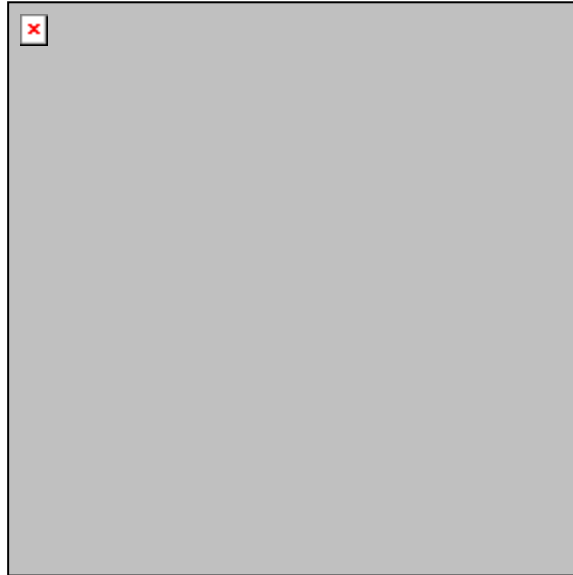
6. The user inspectorate must have adequate liability insurance unless liability is assumed by the group of which it is part.

7. The personnel of the user inspectorate must observe professional secrecy with regard to all information gained in carrying out their tasks (except vis-à-vis the competent administrative authorities of the State in which their activities are carried out) under the Directive or any provision of national law giving effect to it.

ANNEX VI

CE MARKING

The CE marking consists of the initials «CE» taking the following form:



If the CE marking is reduced or enlarged the proportions given in the above graduated drawing must be respected.

The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm.

↓ 97/23/EC (adapted)

ANNEX VII

☒ EU ☒ DECLARATION OF CONFORMITY

The ~~EC~~ ☒ EU ☒ declaration of conformity ~~must~~ ☒ shall ☒ contain the following particulars:

↓ new

1. No ... (unique identification of the pressure equipment):

2. Pressure equipment/pressure equipment model (product, batch, type or serial number):

↓ 97/23/EC (adapted)

2.3 ~~n~~ Name and address of the manufacturer ☒ and, where applicable, ☒ or ~~of~~ his authorized representative ~~established within the Community~~;

↓ new

3. This declaration of conformity is issued under the sole responsibility of the manufacturer.

4. Object of the declaration (identification of pressure equipment allowing traceability. It may, where necessary for the identification of the pressure equipment, include an image:

↓ 97/23/EC (adapted)

- description of the pressure equipment ~~or assembly~~;

↓ 97/23/EC (adapted)

- conformity assessment procedure followed;
- in the case of assemblies, description of the pressure equipment constituting the assembly, and the conformity assessment procedures followed;
- where appropriate, ☒ the ☐ name, and address ☒ and number ☐ of the notified body which carried out the inspection ☒ and the number of the certificate issued ☐.

↓ 97/23/EC (adapted)

- where appropriate, a reference to the ~~EC-type~~ ☒ EU-type ☐ examination certificate, ~~EC-design~~ ☒ EU-design ☐ examination certificate or ~~EC~~ ☒ EU ☐ certificate of conformity;

↓ new

5. The object of the declaration described above is in conformity with the relevant Union harmonisation legislation: (reference to the other Union Directives applied):

6. References to the relevant harmonised standards used or references to the specifications in relation to which conformity is declared:

↓ 97/23/EC

~~where appropriate, name and address of the notified body monitoring the manufacturer's quality assurance system,~~

↓ new

8. Additional information:

Signed for and on behalf of:

(place and date of issue):

(name, function) (signature):

↓ 97/23/EC

– ~~where appropriate, the references of the harmonized standards applied,~~

– ~~where appropriate, other technical standards and specifications used,~~

↓ 97/23/EC (adapted)

– ~~And~~ ☒ where appropriate, ☒ particulars of the signatory authorized to sign the legally binding declaration for the manufacturer or his authorized representative established within the Community.

– ~~where appropriate, the references of the other Community Directives applied.~~

↑

ANNEX V

PART A

Repealed Directive with its successive amendments (referred to in Article 50)

Directive 97/23/EC of the European Parliament and of the Council	(OJ L 181, 9.7.1997, p.1)
Regulation (EC) No 1882/2003 of the European Parliament and of the Council	(OJ L 284, 31.10.2003, p. 1)
Regulation (EU) No 1025/2012 of the European Parliament and of the Council	(OJ L 316, 14.11.2012, p. 12)

PART B

Time-limits for transposition into national law and application (referred to in Article 15)

Directive	Time-limit for transposition	Date of application
97/23/EC	29 May 1999	29 November 1999 ⁴⁵

⁴⁵ In accordance with Article 20(3) of Directive 97/23/EC, Member States shall permit the putting into service of pressure equipment and assemblies which comply with the regulations in force in their territory at the date of application of the Directive beyond that date.

ANNEX VI

<i>CORRELATION TABLE</i>	
Directive 97/23/EC	This Directive
Article 1(1)	Article 1(1)
Article 1(2)	Article 2 (1) to (14)
—	Article 2 (15) to (31)
Article 1(3)	Article 1(2)
Article 2	Article 3
Article 3	Article 4
Article 4	Article 5
—	Article 6
—	Article 7
—	Article 8
—	Article 9
—	Article 10
—	Article 11
Article 5(1)	Article 12(2)
Article 5(2)	—
Article 5(3)	
—	Article 12(1)
Article 7(1)	Article 40
Article 7(2)	Article 39(1)
—	Article 39(2)
Article 7(3)	Article 39(3)
Article 7(4)	Article 39(4)
Article 8	—

Article 9(1)	Article 13(1) introductory sentence
Article 9(2) point 1	_____
_____	Article 13(1) (a)
Article 9(2) point 2	Article 13(1) (b)
Article 9(3)	Article 13(2)
Article 10	Article 14
Article 11(1)	Article 15(1)
Article 11(2)	Article 15(2)
Article 11(3)	Article 15(3)
Article 11(4)	Article 12(3)
_____	Article 15(4)
Article 11(5)	Article 15(5)
_____	Article 15(6)
Article 12	_____
Article 13	_____
Article 14(1)	Article 16(1)
Article 14(2)	Article 5(3)
Article 14(3) to (8)	Article 16(2) to (7)
Article 14(9) and (10)	_____
_____	Article 17
_____	Article 18
Article 15(1)	_____
Article 15(2)	Article 19(1)
Article 15(3)	Article 19(2)
Article 15(4) and (5)	_____
_____	Article 19(3) to (5)
_____	Article 20

—	Article 21
—	Article 22
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—	Article 33
—	Article 34
—	Article 35
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—	Article 37
—	Article 38
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Article 17	—
Article 18	—
—	Article 41
—	Article 42
Article 19	—
Article 20 (1) to (2)	—
Article 20(3)	Article 43(1)
—	Article 43(2) and (3)

—	Article 44
—	Article 45
—	Article 46
Article 21	Article 47
Annex I	Annex I
Annex II	Annex II
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Annex III, Module A	Annex III, point 1, Module A
Annex III, Module A1	Annex III, point 2, Module A2
Annex III, Module B	Annex III, point 3.1, Module B, EU-type examination – combination of production type and design type
Annex III, Module B1	Annex III, point 3.2, Module B, EU-type examination – design type
Annex III, Module C1	Annex III, point 4, Module C2
Annex III, Module D	Annex III, point 5, Module D
Annex III, Module D1	Annex III, point 6, Module D1
Annex III, Module E	Annex III, point 7, Module E
Annex III, Module E1	Annex III, point 8, Module E1
Annex III, Module F	Annex III, point 9, Module F
Annex III, Module G	Annex III, point 10, Module G
Annex III, Module H	Annex III, point 11, Module H
Annex III, Module H1	Annex III, point 12, Module H1
Annex IV	—
Annex V	—
Annex VI	—
Annex VII	Annex IV
—	Annex V

_____	Annex VI
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