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#### COVER NOTE

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From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	12 March 2019
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union

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Subject:	COMMISSION DELEGATED REGULATION (EU) .../... of 12.3.2019 on unmanned aircraft systems and on third-country operators of unmanned aircraft systems

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Delegations will find attached document C(2019) 1821 final.

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Encl.: C(2019) 1821 final



Brussels, 12.3.2019  
C(2019) 1821 final

**COMMISSION DELEGATED REGULATION (EU) .../...**

**of 12.3.2019**

**on unmanned aircraft systems and on third-country operators of unmanned aircraft systems**

## **EXPLANATORY MEMORANDUM**

### **1. CONTEXT OF THE DELEGATED ACT**

With the adoption of the EASA new basic Regulation, the EU is competent for all unmanned aircraft, irrespective of their weight. Consequently, it is necessary to set out the requirements that address the risks posed by the operation of such unmanned aircraft, taking full account of other applicable Union harmonisation legislation, as well as the type of aircraft and category of operations concerned. The main objective of this initiative is to establish detailed rules for unmanned aircraft where it concerns their design, engines, propellers, parts, and equipment to control the aircraft remotely.

### **2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT**

In accordance with Article 128(4) of Regulation (EU) 2018/1139, before adopting a delegated act, the Commission consulted experts designated by each Member State in accordance with principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making. The draft of the delegated act was presented to the Air Safety experts group, which includes representatives from the Member States at its meetings in October and December 2018. The draft of the delegated act is based on the final opinion produced by EASA on 6 February 2018 which followed its Notice of Proposed Amendment for a new regulation on drones and which has been supported by an impact assessment and stakeholder consultations.

### **3. LEGAL ELEMENTS OF THE DELEGATED ACT**

The Commission is empowered to adopt delegated acts, in accordance with Article 128, laying down detailed rules with regard to the necessary features and functionalities related to unmanned aircraft.

# COMMISSION DELEGATED REGULATION (EU) .../...

of 12.3.2019

## on unmanned aircraft systems and on third-country operators of unmanned aircraft systems

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91<sup>1</sup>, and in particular Article 58 and Article 61 thereof,

Whereas:

- (1) The unmanned aircraft systems ('UAS') whose operation presents the lowest risks and that belong to the 'open' category of operations should not be subject to classic aeronautical compliance procedures. The possibility to establish Community harmonisation legislation as referred to in paragraph 6 of Article 56 of Regulation (EU) 2018/1139 should be used for those UAS. Consequently, it is necessary to set out the requirements that address the risks posed by the operation of those UAS, taking full account of other applicable Union harmonisation legislation.
- (2) These requirements should cover the essential requirements provided for in Article 55 of Regulation (EU) 2018/1139, in particular as regards the specific features and functionalities necessary to mitigate risks pertaining to the safety of the flight, privacy, and protection of personal data, security or the environment, arising from the operation of these UAS.
- (3) When manufacturers place a UAS on the market with the intention to make it available for operations under the 'open' category and therefore affix a class identification label on it, they should ensure compliance of the UAS with the requirements of that class.
- (4) Considering the good level of safety achieved by model aircraft already made available on the market, it is appropriate to create the C4 class of UAS which should not be subject to disproportionate technical requirements for the benefit of model aircraft operators.
- (5) This Regulation should also apply to UAS, which are considered as toys within the meaning of Directive 2009/48/EC of the European Parliament and of the Council<sup>2</sup>. Those UAS should also comply with Directive 2009/48/EC. That compliance

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<sup>1</sup> OJ L 212, 22.8.2018, p.1.

<sup>2</sup> Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1).

requirement should be taken into account when defining additional safety requirements under this Regulation.

- (6) UAS that are not toys within the meaning of Directive 2009/48/EC should comply with the relevant essential health and safety requirements set out in Directive 2006/42/EC of the European Parliament and of the Council<sup>3</sup> in so far as this Directive applies to them, to the extent that those health and safety requirements are not intrinsically linked to the safety of the flight by UAS. Where those health and safety requirements are intrinsically linked to the safety of the flight, only this Regulation should apply.
- (7) Directive 2014/30/EU<sup>4</sup> and Directive 2014/53/EU<sup>5</sup> of the European Parliament and of the Council should not apply to unmanned aircraft that are subject to certification according to Regulation (EU) 2018/1139, are exclusively intended for airborne use and intended to be operated only on frequencies allocated by the Radio Regulations of the International Telecommunication Union for protected aeronautical use.
- (8) Directive 2014/53/EU should apply to unmanned aircraft that are not subject to certification and are not intended to be operated only on frequencies allocated by the Radio Regulations of the International Telecommunication Union for protected aeronautical use, if they intentionally emit and/or receive electromagnetic waves for the purpose of radio communication and/or radiodetermination at frequencies below 3000 GHz.
- (9) Directive 2014/30/EU should apply to unmanned aircraft that are not subject to certification and are not intended to be operated only on frequencies allocated by the Radio Regulations of the International Telecommunication Union for protected aeronautical use, if they do not fall within the scope of Directive 2014/53/EU.
- (10) Decision No 768/2008/EC of the European Parliament and of the Council<sup>6</sup> sets out common principles and horizontal provisions intended to apply to marketing of products that are subject to relevant sectorial legislation. In order to ensure consistency with other sectorial product legislation, the provisions on the marketing of UAS intended to be operated in the ‘open’ category should be aligned with the framework established by Decision 768/2008/EC.
- (11) Directive 2001/95/EC<sup>7</sup> applies to safety risks of UAS so far as there are no specific provisions with the same objective in rules of Union law governing the safety of the products concerned.
- (12) This Regulation should apply to all forms of supply, including distance selling.

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<sup>3</sup> Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24).

<sup>4</sup> Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (OJ L 96, 29.3.2014, p. 79).

<sup>5</sup> Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p. 62)

<sup>6</sup> 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/EEC (OJ L 218, 13.8.2008, p. 82).

<sup>7</sup> Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (OJ L 11, 15.1.2002, p. 4).

- (13) Member States should take the necessary steps to ensure that UAS intended to be operated in the ‘open’ category are made available on the market and put into service only where they do not compromise the health and safety of persons, domestic animals or property, when normally used.
- (14) In order to provide citizens with high level of environmental protection, it is necessary to limit the noise emissions to the greatest possible extent. Sound power limitations applicable to UAS intended to be operated in the ‘open’ category might be reviewed at the end of the transitional periods as defined in Regulation (EU) .../... [IR].
- (15) Special attention should be paid to ensure compliance of products in the context of an increase of e-commerce. To that end, Member States should be encouraged to pursue cooperation with the competent authorities in third countries and to develop cooperation between market surveillance authorities and customs authorities. Market surveillance authorities should make use, when possible, of the ‘notice and action’ procedures and establish cooperation with their national authorities competent for the implementation of Directive 2000/31/EC of the European Parliament and of the Council<sup>8</sup>. They should establish close contacts allowing rapid response with key intermediaries that provide hosting services for products sold online.
- (16) In order to ensure a high level of protection of public interest, such as health safety, and to guarantee fair competition on the Union market, economic operators should be responsible for the compliance of UAS intended to be operated in the ‘open’ category with the requirements laid down in this Regulation, in relation to their respective roles in the supply and distribution chain. Therefore, it is necessary to provide a clear and proportionate distribution of obligations, which corresponds to the role of each economic operator in the supply and distribution chain.
- (17) In order to facilitate communication between economic operators, national market surveillance authorities and consumers, economic operators supplying or distributing UAS intended to be operated in the ‘open’ category should provide a website address in addition to the postal address.
- (18) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the conformity assessment procedure of UAS intended to be operated in the ‘open’ category. Conformity assessment should therefore remain solely the obligation of the manufacturer.
- (19) This Regulation should apply to any UAS intended to be operated in the ‘open’ category that is new to the Union market, whether a new UAS made by a manufacturer established in the Union or a new or second-hand UAS imported from a third country.
- (20) It is necessary to ensure that UAS from third countries entering the Union market comply with the requirements of this Regulation if they are intended to be operated in the ‘open’ category. In particular, it should be ensured that manufacturers carry out appropriate conformity assessment procedures. Provision should therefore be made for importers to make sure that the UAS they place on the market comply with the requirements of this Regulation and that they do not place on the market UAS which do not comply with these requirements or present a risk. Provision should also be made for importers to make sure that the conformity assessment procedures have been

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<sup>8</sup> Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (‘Directive on electronic commerce’) (OJ L 178, 17.7.2000, p. 1).

carried out and that the CE marking and technical documentation drawn up by the manufacturers is available for inspection by the competent national authorities.

- (21) The distributor who makes a UAS intended to be operated in the ‘open’ category available on the market should act with due care to ensure that its handling of the product does not adversely affect its compliance. Both importers and distributors are expected to act with due care in relation to the requirements applicable when placing or making products available on the market.
- (22) When placing on the market a UAS intended to be operated in the ‘open’ category, every importer should indicate on the UAS his name, registered trade name or registered trademark and the address at which he can be contacted. Exceptions should be provided for cases where the size of the UAS does not allow this. This includes cases where the importer would have to open the packaging to put his name and address on the UAS.
- (23) Any economic operator that either places a UAS intended to be operated in the ‘open’ category on the market under his own name or trademark, or modifies a UAS intended to be operated in the ‘open’ category in such a way that compliance with the applicable requirements may be affected, should be considered to be the manufacturer and should assume the obligations of the manufacturer.
- (24) 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 the necessary information relating to the UAS intended to be operated in the ‘open’ category.
- (25) Ensuring the traceability of a UAS intended to be operated in the ‘open’ category throughout the whole supply chain helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates the market surveillance authorities’ task of tracing economic operators who make non-compliant UAS available on the market.
- (26) This Regulation should be limited to the setting out of the essential requirements. In order to facilitate the assessment of conformity of UAS intended to be operated in the ‘open’ category with those requirements, it is necessary to provide for a presumption of conformity for products, which are in conformity with harmonised standards that are adopted in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council<sup>9</sup> for the purpose of setting out detailed technical specifications of those requirements.
- (27) The essential requirements applicable to UAS intended to be operated in the ‘open’ category should be worded precisely enough to create legally binding obligations. They should be formulated so as to make it possible to assess conformity with them even in the absence of harmonised standards or where the manufacturer chooses not to apply a harmonised standard.

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<sup>9</sup> 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 Council (OJ L 316, 14.11.2012, p. 12).

- (28) Regulation (EU) No 1025/2012 provides for a procedure for objections to harmonised standards where those standards do not entirely satisfy the requirements of the harmonisation legislation applicable to UAS intended to be operated in the ‘open’ category under this Regulation. This procedure should apply where appropriate in relation to standards which reference have been published in the Official Journal as providing presumption of conformity with the requirements laid down in this Regulation.
- (29) To enable economic operators to demonstrate and the competent authorities to ensure that UAS intended to be operated in the ‘open’ category made available on the market comply with the essential requirements, it is necessary to provide for conformity assessment procedures. Decision No 768/2008/EC sets out 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-sectorial coherence and to avoid ad hoc variants of conformity assessment, conformity assessment procedures should be chosen from among those modules.
- (30) Market surveillance authorities and UAS operators should have easy access to the EU declaration of conformity. In order to fulfil this requirement, manufacturers should ensure that each UAS intended to be operated in the ‘open’ category is accompanied either by a copy of the EU declaration of conformity or by the internet address at which the EU declaration of conformity can be accessed.
- (31) To ensure effective access to information for market surveillance purposes, the information required to identify all applicable Union acts for UAS intended to be operated in the ‘open’ category should be available in a single EU declaration of conformity. In order to reduce the administrative burden on economic operators, it should be possible for that single EU declaration of conformity to be a dossier made up of relevant individual declarations of conformity.
- (32) The CE marking indicating the conformity of a product is the visible consequence of a whole process of conformity assessment in the broad sense. The general principles governing the CE marking are set out in Regulation (EC) No 765/2008 of the European Parliament and of the Council<sup>10</sup>. Rules governing the affixing of the CE marking to UAS intended to be operated in the ‘open’ category should be laid in this Regulation.
- (33) Some UAS classes intended to be operated in the ‘open’ category covered by this Regulation require the intervention of conformity assessment bodies. Member States should notify the Commission of these.
- (34) It is necessary to ensure a uniformly high level of performance of bodies performing conformity assessments of UAS intended to be operated in the ‘open’ category throughout the Union, and that all such bodies perform their functions at the same level and under conditions of fair competition. Therefore, obligatory requirements should be set for conformity assessment bodies wishing to be notified in order to provide conformity assessment services.

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<sup>10</sup> 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 339/93 (OJ L 218, 13.8.2008, p. 30).

- (35) If a conformity assessment body demonstrates conformity of UAS intended to be operated in the ‘open’ category with the criteria laid down in harmonised standards, it should be presumed to comply with the corresponding requirements set out in this Regulation.
- (36) 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 notified bodies.
- (37) Regulation (EC) No 765/2008 sets out 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 sets out the general principles of the CE marking. The system set out in this Regulation should be complemented by the accreditation system provided for in Regulation (EC) No 765/2008.
- (38) Transparent accreditation as provided for in Regulation (EC) No 765/2008, ensuring the necessary level of confidence in certificates of conformity, should be used by national public authorities throughout the Union as the means of demonstrating the technical competence of conformity assessment bodies.
- (39) 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 UAS intended to be operated in the ‘open’ category to be placed on the Union market, it is essential that conformity assessment subcontractors and subsidiaries fulfil the same requirements as notified bodies do in relation to the performance of conformity assessment tasks. Therefore, it is important that the assessment of the competence and performance of bodies to be notified, and the monitoring of bodies already notified, also cover activities carried out by subcontractors and subsidiaries.
- (40) 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.
- (41) Since notified 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.
- (42) In the interests of competitiveness, it is crucial that notified bodies apply the conformity assessment procedures without creating unnecessary administrative burden for economic operators. For the same reason, and also to ensure equal treatment of economic operators, consistency in the technical application of the conformity assessment procedures needs to be ensured. This can best be achieved through appropriate coordination and cooperation between notified bodies.
- (43) Interested parties should have the right to appeal against the result of a conformity assessment carried out by a notified body. It is important to ensure that an appeal procedure against all decisions taken by notified bodies is available.
- (44) Manufacturers should take all appropriate measures to ensure that UAS intended to be operated in the ‘open’ category may be placed on the market only if, when properly stored and used for their intended purpose or under conditions, which can be reasonably foreseen, it does not endanger people’s health or safety. UAS intended to be operated in the ‘open’ category should be considered as non-compliant with the essential requirements set out in this Regulation only under conditions of use which

can be reasonably foreseen, that is when such use could result from lawful and readily predictable human behaviour.

- (45) In order to ensure legal certainty, it is necessary to clarify that the rules on Union market surveillance and control of products entering the Union market provided for in Regulation (EC) No 765/2008, including the provisions regarding the exchange of information through the Rapid Alert System (RAPEX), apply to UAS intended to be operated in the ‘open’ category. This Regulation should not prevent Member States from choosing the competent authorities to carry out those tasks. In order to ensure a smooth transition as regards the implementation of this Regulation, appropriate transitional measures should be provided.
- (46) UAS whose operation present the highest risks should be subject to certification. This Regulation should therefore define the conditions under which the design, production and maintenance of UAS should be subject to certification. Those conditions are linked to a higher risk of harm to third persons in case of accidents and therefore certification should be required for UAS designed to transport people, UAS designed to transport dangerous goods and for UAS that has any dimension above 3 m and is designed to be operated over assemblies of people. Certification of UAS used in the ‘specific’ category of operations defined in Regulation (EU) ...../... [IR] should also be required if, following a risk assessment, an operational authorisation issued by the competent authority considers that the risk of the operation cannot be adequately mitigated without the certification of the UAS.
- (47) UAS placed on the market and intended to be operated in the ‘open’ category and bearing a class identification label should comply with the certification requirements for UAS operated in the ‘specific’ or ‘certified’ categories of operations, as applicable, if those UAS are used outside the ‘open’ category of operations.
- (48) UAS operators that have their principal place of business, are established, or are resident in a third country and that conduct UAS operations within the single European sky airspace should be subject to this Regulation.
- (49) The measures provided for in this Regulation are based on Opinion No 01/2018<sup>11</sup> issued by the European Union Aviation Safety Agency (EASA) in accordance with Article 65 of Regulation (EU) 2018/1139,

HAS ADOPTED THIS REGULATION:

## **CHAPTER I**

### **General Provisions**

#### *Article 1* *Subject matter*

1. This Regulation lays down the requirements for the design and manufacture of unmanned aircraft systems (‘UAS’) intended to be operated under the rules and

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<sup>11</sup> EASA Opinion No 01/2018 ‘Introduction of a regulatory framework for the operation of unmanned aircraft systems in the ‘open’ and ‘specific’ categories’ (RMT.0230), available at <https://www.easa.europa.eu/document-library/opinions>.

conditions defined in Regulation (EU) .../... [IR]<sup>12</sup> and of remote identification add-ons. It also defines the type of UAS whose design, production and maintenance shall be subject to certification.

2. It also establishes rules on making UAS intended for use in the ‘open’ category and remote identification add-ons available on the market and on their free movement in the Union.
3. This Regulation also lays down rules for third-country UAS operators, when they conduct a UAS operation pursuant to Regulation (EU) .../... [IR] within the single European sky airspace.

## *Article 2* *Scope*

1. Chapter II of this Regulation applies to the following products:
  - (a) UAS intended to be operated under the rules and conditions applicable to the ‘open’ category of UAS operations pursuant to Regulation (EU) .../... [IR], except privately built UAS, and bearing a class identification label as set out in Parts 1 to 5 of the Annex to this Regulation indicating to which of the five UAS classes referred to in Regulation (EU) .../... [IR] it belongs to;
  - (b) remote identification add-ons as set out in Part 6 of the Annex to this Regulation.
2. Chapter III of this Regulation applies to UAS operated under the rules and conditions applicable to the ‘certified’ and ‘specific’ categories of UAS operations pursuant to Regulation (EU) .../... [IR].
3. Chapter IV of this Regulation applies to UAS operators that have their principal place of business, are established, or reside in a third country, if the UAS are operated in the Union.
4. This Regulation does not apply to UAS intended to be exclusively operated indoors.

## *Article 3* *Definitions*

For the purposes of this Regulation, the following definitions apply:

- (1) ‘unmanned aircraft’ (‘UA’) means any aircraft operating or designed to operate autonomously or to be piloted remotely without a pilot on board;
- (2) ‘equipment to control unmanned aircraft remotely’ means any instrument, equipment, mechanism, apparatus, appurtenance, software or accessory that is necessary for the safe operation of a UA other than a part and which is not carried on board that UA;
- (3) ‘unmanned aircraft system’ (‘UAS’) means an unmanned aircraft and the equipment to control it remotely;

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<sup>12</sup> OJ reference to be added when the draft Commission Regulation laying down rules and procedures for the operation of unmanned aircraft will be adopted. For referencing purposes, ‘Regulation (EU) .../... [IR]’ is used in the proposed draft Regulation.

- (4) ‘unmanned aircraft system operator’ (‘UAS operator’) means any legal or natural person operating or intending to operate one or more UAS;
- (5) ‘open’ category’ means a category of UAS operations that is defined in Article 4 of Regulation ... [IR];
- (6) ‘specific’ category means a category of UAS operations that is defined in Article 5 of Regulation ... [IR];
- (7) ‘certified’ category means a category of UAS operation that is defined in Article 6 of Regulation ... [IR];
- (8) ‘Union harmonisation legislation’ means any Union legislation harmonising the conditions for placing products on the market;
- (9) ‘accreditation’ means accreditation as defined in paragraph 10 of Article 2 of Regulation (EC) No 765/2008;
- (10) ‘conformity assessment’ means the process demonstrating whether the specified requirements relating to a product have been fulfilled;
- (11) ‘conformity assessment body’ means a body that performs conformity assessment activities including calibration, testing, certification and inspection;
- (12) ‘CE marking’ means a marking by which the manufacturer indicates that the product is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing;
- (13) ‘manufacturer’ means any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under their name or trademark;
- (14) ‘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;
- (15) ‘importer’ means any natural or legal person established within the Union who places a product from a third country on the Union market;
- (16) ‘distributor’ means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market;
- (17) ‘economic operators’ means the manufacturer, the authorised representative of the manufacturer, the importer, and the distributor of the UAS;
- (18) ‘making available on the market’ means any supply of a product for distribution, consumption or use in the Union market in the course of a commercial activity, whether in exchange of payment or free of charge;
- (19) ‘placing on the market’ means the first making available of a product on the Union market;
- (20) ‘harmonised standard’ means a harmonised standard as defined in point (c) of Article 2(1) of Regulation (EU) No 1025/2012;
- (21) ‘technical specification’ means a document that establishes technical requirements to be fulfilled by a product, process or service;
- (22) ‘privately built UAS’ means a UAS assembled or manufactured for the builder’s own use, not including UAS assembled from a set of parts placed on the market by the manufacturer as a single ready-to-assemble kit;

- (23) ‘market surveillance authority’ means an authority of a Member State responsible for carrying out market surveillance on its territory;
- (24) ‘recall’ means any measure aimed at achieving the return of a product that has already been made available to the end user;
- (25) ‘withdrawal’ means any measure aimed at preventing a product in the supply chain from being made available on the market;
- (26) ‘single European sky airspace’ means airspace above the territory to which the Treaties apply, as well as any other airspace where Member States apply Regulation (EC) No 551/2004 of the European Parliament and of the Council<sup>13</sup> in accordance with paragraph 3 of Article 1 of that Regulation;
- (27) ‘remote pilot’ means a natural person responsible for safely conducting the flight of a UA by operating its flight controls, either manually or, when the UA flies automatically, by monitoring its course and remaining able to intervene and change its course at any time;
- (28) ‘maximum take-off mass’ (‘MTOM’) means the maximum UA mass, including payload and fuel, as defined by the manufacturer or the builder, at which the UA can be operated;
- (29) ‘payload’ means any instrument, mechanism, equipment, part, apparatus, appurtenance, or accessory, including communications equipment, that is installed in or attached to the aircraft, and is not used or intended to be used in operating or controlling an aircraft in flight, and is not part of an airframe, engine, or propeller;
- (30) ‘follow-me mode’ means a mode of operation of a UAS where the unmanned aircraft constantly follows the remote pilot within a predetermined radius;
- (31) ‘direct remote identification’ means a system that ensures the local broadcast of information about a UA in operation, including the marking of the UA, so that this information can be obtained without physical access to the UA;
- (32) ‘geo-awareness’ means a function that, based on the data provided by Member States, detects a potential breach of airspace limitations and alerts the remote pilots so that they can take effective immediate and action to prevent that breach;
- (33) ‘sound power level  $L_{WA}$ ’ means the A-weighted sound power in dB in relation to 1 pW as defined in EN ISO 3744:2010;
- (34) ‘measured sound power level’ means a sound power level as determined from measurements as laid down in Part 13 of the Annex; measured values may be determined either from a single UA representative for the type of equipment or from the average of a number of UA;
- (35) ‘guaranteed sound power level’ means a sound power level determined in accordance with the requirements laid down in Part 13 of the Annex which includes the uncertainties due to production variation and measurement procedures and where the manufacturer, or his authorised representative established in the Community, confirms that according to the technical instruments applied and referred to in the technical documentation it is not exceeded;

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<sup>13</sup> Regulation (EC) No 551/2004 of the European Parliament and of the Council of 10 March 2004 on the organisation and use of the airspace in the single European sky (OJ L 96, 31.3.2004, p. 20).

- (36) 'hovering' means staying in the same geographical position in the air;
- (37) 'assemblies of people' means gatherings where persons are unable to move away due to the density of the people present.

## CHAPTER II

### UAS intended to be operated in the 'open' category and remote identification add-ons

#### SECTION 1

#### PRODUCT REQUIREMENTS

##### *Article 4 Requirements*

1. The products referred to in paragraph 1 of Article 2 shall meet the requirements set out in Parts 1 to 6 of the Annex.
2. UAS that are not toys within the meaning of Directive 2009/48/EC shall comply with the relevant health and safety requirements set out in Directive 2006/42/EC only in relation to risks other than those linked to the safety of the UA flight.
3. Any updates of software of the products that have already been made available on the market may be made only if such updates do not affect the compliance of the product.

##### *Article 5*

##### *Making available on the market and free movement of products*

1. Products shall only be made available on the market if they satisfy the requirements of this Chapter and do not endanger the health or safety of persons, animals or property.
2. Member States shall not prohibit, restrict or impede, for the aspects covered by this Chapter, the making available on the market of products that comply with this Chapter.

#### SECTION 2

#### OBLIGATIONS OF ECONOMIC OPERATORS

##### *Article 6 Obligations of manufacturers*

1. When placing their product on the Union market, manufacturers shall ensure that it has been designed and manufactured in compliance with the requirements set out in Parts 1 to 6 of the Annex.
2. Manufacturers shall draw up the technical documentation provided for in Article 17 and carry out the relevant conformity assessment procedure referred to in Article 13 or have it outsourced.

Where compliance of the product with the requirements set out in Parts 1 to 6 of the Annex has been demonstrated by that conformity assessment procedure,

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 product has been placed on the market.
4. Manufacturers shall ensure that procedures are in place for series production to remain in conformity with this Chapter. Changes in product design, characteristics or software, and changes in the harmonised standards or in technical specifications by reference to which conformity of a product is declared shall be adequately taken into account.

When deemed appropriate with regard to the risks presented by a product, manufacturers shall, to protect the health and safety of consumers, carry out sample testing of marketed products, investigate, and, if necessary, keep a register of complaints, of non-conforming products and product recalls and shall keep distributors informed of any such monitoring.

5. Manufacturers of UAS shall ensure that the UA bears a type within the meaning of Decision 768/2008/EC and a unique serial number allowing for its identification, and if applicable, compliant with the requirements defined in the corresponding Parts 2 to 4 of the Annex. Manufacturers of remote identification add-ons shall ensure that the remote identification add-on bears a type and a unique serial number allowing for their identification and compliant with the requirements defined in Part 6 of the Annex. In both cases, manufacturers shall ensure that a unique serial number is also affixed to the EU declaration of conformity or to the simplified EU declaration of conformity referred to in Article 14.
6. Manufacturers shall indicate on the product their name, registered trade name or registered trademark, website address and the postal address at which they can be contacted or, where that is not possible, on its packaging, or in a document accompanying it. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be indicated in a language easily understood by end users and market surveillance authorities.
7. Manufacturers shall ensure that the product is accompanied by the manual and information notice required by Parts 1 to 6 of the Annex in a language which can be easily understood by consumers and other end users, as determined by the Member State concerned. Such manual and information notice, as well as any labelling, shall be clear, understandable and legible.
8. Manufacturers shall ensure that each product is accompanied by a copy of the EU declaration of conformity or by a simplified EU declaration of conformity. Where a simplified EU declaration of conformity is provided, it shall contain the exact internet address where the full text of the EU declaration of conformity can be obtained.
9. Manufacturers who consider or have reason to believe that products which they have placed on the market are not in conformity with this Chapter shall immediately take the corrective measures necessary to bring that product into conformity, to withdraw it or recall it, if appropriate. Where the product presents a risk, manufacturers shall immediately inform the market surveillance authorities of the Member States in which they made the product available on the market to that effect, giving details, in particular, of the non-compliance, of any corrective measures taken and of the results thereof.

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

*Article 7*  
*Authorised representatives*

1. A manufacturer may, by a written mandate, appoint an authorised representative.  
The obligations laid down in paragraph 1 of Article 6 and the obligation to draw up the technical documentation referred to in paragraph 2 of Article 6 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 market surveillance authorities for 10 years after the product has been placed on the Union market;
  - (b) further to a reasoned request from a market surveillance or border control authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the product;
  - (c) cooperate with the market surveillance or border control authorities, at their request, on any action taken to eliminate the non-conformity of the products covered by the authorised representative's mandate or the safety risks posed by it.

*Article 8*  
*Obligations of importers*

1. Importers shall only place products compliant with the requirements set out in this Chapter on the Union market.
2. Before placing a product on the Union market, importers shall ensure that:
  - (a) the appropriate conformity assessment procedure referred to in Article 13 has been carried out by the manufacturer;
  - (b) the manufacturer has drawn up the technical documentation referred to in Article 17;
  - (c) the product bears the CE marking and, when required, the UA class identification label and the indication of the sound power level;
  - (d) the product is accompanied by the documents referred to in paragraph 7 and 8 of Article 6;
  - (e) the manufacturer has complied with the requirements set out in paragraphs 5 and 6 of Article 6.

Where an importer considers or has reasons to believe that a product is not in conformity with the requirements set out in Parts 1 to 6 of the Annex, he shall not

place the product on the market until it has been brought into conformity. Furthermore, where the product presents a risk for the health and safety of consumers and third parties, the importer shall inform the manufacturer and the competent national authorities to that effect.

3. Importers shall indicate on the product their name, registered trade name or registered trademark, website and the postal address at which they can be contacted or, where that is not possible, on its packaging or in a document accompanying the product. The contact details shall be in a language easily understood by end users and market surveillance authorities.
4. Importers shall ensure that the product is accompanied by the manual and information notice required by Parts 1 to 6 of the Annex in a language which can be easily understood by consumers and other end users, as determined by the Member State concerned. That manual and information notice, as well as any labelling, shall be clear, understandable and legible.
5. Importers shall ensure that, while the product is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the requirements set out in Article 4.
6. When deemed appropriate with regard to the risks presented by a product, importers shall, in order to protect the health and safety of end users and third parties, carry out sample testing of products made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming of products and product recalls, and shall keep distributors informed of any such monitoring.
7. Importers who consider or have reason to believe that a product which they have placed on the market is not in conformity with the applicable Union harmonisation legislation shall immediately take the corrective measures necessary to bring that product into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the product presents a risk, importers shall immediately inform the market surveillance authorities of the Member States in which they made the product available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.
8. Importers shall, for 10 years after the product 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 the competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the product in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by the product which they have placed on the market.

*Article 9*  
*Obligations of distributors*

1. When making a product available on the Union market, distributors shall act with due care in relation to the requirements set out in this Chapter.

2. Before making a product available on the market, distributors shall verify that the product bears the CE marking and, when applicable, the UA class identification label and the indication of the sound power level, is accompanied by the documents referred to in paragraphs 7 and 8 of Article 6 and that the manufacturer and the importer have complied with the requirements set out in paragraphs 5 and 6 of Article 6 and in paragraph 3 of Article 8).

Distributors shall ensure that the product is accompanied by the manual and information notice required by Parts 1 to 6 of the Annex in a language which can be easily understood by consumers and other end users, as determined by the Member State concerned. That manual and information notice, as well as any labelling, shall be clear, understandable and legible.

Where a distributor considers or has reason to believe that a product is not in conformity with the requirements set out in Article 4, he shall not make the product available on the market until it has been brought into conformity. Furthermore, where the product presents a risk, the distributor shall inform the manufacturer or the importer to that effect, as well as the competent market surveillance authorities.

3. Distributors shall ensure that, while a product is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the requirements set out in Article 4.
4. Distributors who consider or have reasons to believe that a product which they have made available on the market is not in conformity with the applicable Union harmonisation legislation shall make sure that the corrective measures necessary to bring that product into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the product presents a risk, distributors shall immediately inform the market surveillance authorities of the Member States in which they made the product available on the market 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 the competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the product. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by the product which they have made available on the market.

#### *Article 10*

##### *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 Chapter and shall be subject to the obligations of manufacturers pursuant to Article 6, where they place a product on the market under their name or trademark or modify the product already placed on the market in such a way that compliance with this Chapter may be affected.

#### *Article 11*

##### *Identification of economic operators*

1. Economic operators shall, on request, identify the following to the market surveillance authorities:
  - (a) any economic operator who has supplied them with a product;
  - (b) any economic operator to whom they have supplied a product.

2. Economic operators shall be able to present the information referred to in paragraph 1:
  - (a) for 10 years after they have been supplied with the product;
  - (b) for 10 years after they have supplied the product.

### **SECTION 3**

#### **CONFORMITY OF THE PRODUCT**

##### *Article 12*

##### *Presumption of conformity*

A product which is 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 requirements covered by those standards or parts thereof set out in Parts 1 to 6 of the Annex.

##### *Article 13*

##### *Conformity assessment procedures*

1. The manufacturer shall perform a conformity assessment of the product using one of the following procedures with a view to establishing its compliance with the requirements set out in Parts 1 to 6 of the Annex. The conformity assessment shall take into account all intended and foreseeable operating conditions.
2. The procedures available to conduct the conformity assessment shall be the following:
  - (a) internal production control as set out in Part 7 of the Annex, when assessing the compliance of a product with the requirements set out in Parts 1, 5 or 6 of the Annex, subject to the condition that the manufacturer has applied harmonised standards, the references of which have been published in the Official Journal of the European Union, for all the requirements for which such standards exist;
  - (b) EU-type examination followed by conformity to type based on internal production control as set out in Part 8 of the Annex;
  - (c) conformity based on full quality assurance as set out in Part 9 of the Annex, excepted when assessing the compliance of a product which is a toy within the meaning of Directive [2009/48/EC](#).

##### *Article 14*

##### *EU declaration of conformity*

1. The EU declaration of conformity referred to in paragraph 8 of Article 6 shall state that compliance of the product with the requirements set out in Parts 1 to 6 of the Annex has been demonstrated and, for UAS, identify its class.
2. The EU declaration of conformity shall have the model structure set out in Part 11 of the Annex, shall contain the elements set out in that Part and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which market the product is placed or made available.

3. The simplified EU declaration of conformity referred to in paragraph 8 of Article 6 shall contain the elements set out in Part 12 of the Annex and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which the product is placed or made available on the market. The full text of the EU declaration of conformity shall be available at the internet address referred to in the simplified EU declaration of conformity in a language or languages required by the Member State in which the product is placed or made available on the market.
4. Where a product 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 Union acts concerned, including their publication references.
5. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the product with the requirements laid down in this Chapter.

#### *Article 15*

#### *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.

#### *Article 16*

#### *Rules and conditions for affixing the CE marking, the identification number of the notified body, the UAS class identification label and the indication of the sound power level*

1. The CE marking shall be affixed visibly, legibly and indelibly to the product or to the data plate attached to it. Where that is not possible or not warranted on account of the size of the product, it shall be affixed to the packaging.
2. The UA class identification label shall be affixed visibly, legibly and indelibly to the UA and its packaging and shall be at least 5 mm high. The affixing to a product of markings, signs or inscriptions which are likely to mislead third parties regarding the meaning or form of the class identification label shall be prohibited.
3. The indication of the sound power level provided for in Part 14 of the Annex shall be affixed, when applicable, visibly, legibly and indelibly on the UA, unless that is not possible or not warranted on account of the size of the product, and on the packaging.
4. The CE marking and, when applicable, the indication of the sound power level and the UA class identification label shall be affixed before the product is placed on the market.
5. The CE marking shall be followed by the identification number of the notified body where the conformity assessment procedure set out in Part 9 of the Annex is applied.  
The identification number of the notified body shall be affixed by the notified body itself or, under its instructions, by the manufacturer or his authorised representative.
6. Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.

*Article 17*  
*Technical documentation*

1. The technical documentation shall contain all relevant data and details of the means used by the manufacturer to ensure that the product complies with the requirements set out in Part 1 to 6 of the Annex. It shall, at least, contain the elements set out in Part 10 of the Annex.
2. The technical documentation shall be drawn up before the product is placed on the market and shall be continuously updated.
3. The technical documentation and correspondence relating to any EU-type examination procedure or the assessment of the quality system of the manufacturer shall be drawn up in an official language of the Member State in which the notified body is established or in a language acceptable to that body.
4. Where the technical documentation does not comply with paragraphs 1, 2 or 3 of this Article, the market surveillance authority may ask the manufacturer or the importer to have a test performed by a body acceptable to the market surveillance authority at the expense of the manufacturer or the importer within a specified period in order to verify compliance of the product with the requirements set out in Parts 1 to 6 of the Annex which applies to it.

**SECTION 4**  
**NOTIFICATION OF CONFORMITY ASSESSMENT BODIES**

*Article 18*  
*Notification*

Member States shall notify the Commission and the other Member States of bodies authorised to carry out third-party conformity assessment tasks under this Chapter.

*Article 19*  
*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, including compliance with Article 24.
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 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 20. 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.

*Article 20*  
*Requirements relating to notifying authorities*

1. A notifying authority shall:
  - (a) be established in such a way that no conflict of interest with conformity assessment bodies occurs;
  - (b) be organised and operated so as to safeguard the objectivity and impartiality of its activities;
  - (c) 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;
  - (d) not offer or provide any activities that conformity assessment bodies perform or consultancy services on a commercial or competitive basis;
  - (e) shall safeguard the confidentiality of the information it obtains;
  - (f) have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

*Article 21*  
*Information obligation on notifying authorities*

1. Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.
2. The Commission shall make that information publicly available.

*Article 22*  
*Requirements relating to notified bodies*

1. For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.
2. A conformity assessment body shall be established under national law of a Member State and have legal personality.
3. A conformity assessment body shall be a third-party body independent of the organisation 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 the product 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 product which they assess, nor the representative of any of those parties. This shall not preclude the use of the assessed product that is necessary for the operations of the conformity assessment body or the use of such product 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 product, 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 Part 8 or 9 of the Annex 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 product 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 notified 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 in question and the mass or serial nature of the production process.

A conformity assessment body 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 tasks 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 requirements, of the applicable harmonised standards and of the relevant provisions of Union harmonisation legislation;
  - (d) the ability to draw up EU-type examination certificates or quality system approvals, 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 personnel responsible for carrying out the conformity assessment tasks shall be guaranteed.
- The remuneration of the top-level management and of the personnel responsible for carrying out the conformity assessment tasks 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 Member 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 Parts 8 and 9 of the Annex 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 personnel responsible for carrying out the conformity assessment tasks are informed of, the relevant standardisation activities, the regulatory activities in the area of UAS and frequency planning, 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 23*

##### *Presumption of conformity of notified bodies*

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 Article 22 in so far as the applicable harmonised standards cover those requirements.

#### *Article 24*

##### *Subsidiaries of and subcontracting by notified bodies*

1. Where a notified body 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 22 and shall inform the notifying authority accordingly.
2. Notified bodies 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 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 Parts 8 and 9 of the Annex.

#### *Article 25*

##### *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. The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules, and the product for which that body claims to be competent, as well as by an accreditation certificate issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 22.

#### *Article 26*

##### *Notification procedure*

1. Notifying authorities may only notify conformity assessment bodies which have met the requirements laid down in Article 22.
2. They shall notify conformity assessment bodies to 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 product concerned and the relevant accreditation certification.
4. The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within 2 weeks of a notification.
5. Only such a body shall be considered a notified body for the purposes of this Chapter.
6. The notifying authority shall notify the Commission and the other Member States of any subsequent relevant changes to the notification.

#### *Article 27*

##### *Identification numbers and lists of notified bodies*

1. The Commission shall assign an identification number to a notified body.
2. It shall assign a single such number even where the body is notified under several Union acts.
3. The Commission shall make publicly available the list of the bodies notified under this Regulation, including the identification numbers that have been assigned to them and the activities for which they have been notified.

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

*Article 28*  
*Changes to notifications*

1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 22, or that it fails to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw the notification as appropriate, 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 the notification, or where the notified body 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 or kept available for the responsible notifying and market surveillance authorities at their request.

*Article 29*  
*Challenge of the competence of notified bodies*

1. The Commission shall investigate all cases where it has doubts, or doubt is brought to its attention, about the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject.
2. The notifying Member State shall provide the Commission, on request, with all the information relating to the basis for the notification or the maintenance of the competence of the notified 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 does not meet or no longer meets the requirements for notification, it shall inform the notifying Member State accordingly and request it to take the necessary corrective measures, including de-notification if necessary.

*Article 30*  
*Operational obligations of notified bodies*

1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided in Parts 8 and 9 of the Annex.
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 product in question, and the mass or serial nature of the production process.

In doing so, they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the UA or UAS with this Chapter.

3. Where a notified body finds that the requirements set out in Parts 1 to 6 of the Annex or in corresponding harmonised standards or other technical specifications have not been met by a manufacturer, it shall require the manufacturer to take appropriate corrective measures and shall not issue an EU-type examination certificate or a quality system approval.

4. Where, in the course of the monitoring of conformity following the issue of an EU-type examination certificate or a quality system approval, a notified body finds that a product no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the EU-type examination certificate or the quality system approval if necessary.
5. Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any EU-type examination certificates or quality system approvals, as appropriate.

#### *Article 31*

#### *Appeal against decisions of notified bodies*

Notified bodies shall ensure that a transparent and accessible appeal procedure against their decisions is available.

#### *Article 32*

#### *Information obligation on notified bodies*

1. Notified bodies shall inform the notifying authority of the following:
  - (a) any refusal, restriction, suspension or withdrawal of an EU-type examination certificate or a quality system approval in accordance with the requirements of Parts 8 and 9 of the Annex;
  - (b) any circumstances affecting the scope of, or 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 shall, in accordance with the requirements of Parts 8 and 9 of the Annex, provide the other bodies notified under this Chapter carrying out similar conformity assessment activities covering the same categories of UA or UAS with the relevant information on issues relating to negative and, on request, positive conformity assessment results.
3. Notified bodies shall fulfil information obligations under Parts 8 and 9 of the Annex.

#### *Article 33*

#### *Exchange of experience*

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

#### *Article 34*

#### *Coordination of notified bodies*

1. The Commission shall ensure that appropriate coordination and cooperation between bodies notified under this Chapter are put in place and properly operated in the form of a sectorial group of notified bodies.

2. Notified bodies shall participate in the work of that group, directly or by means of designated representatives.

## SECTION 5

### UNION MARKET SURVEILLANCE, CONTROL OF PRODUCTS ENTERING THE UNION MARKET AND UNION SAFEGUARD PROCEDURE

#### *Article 35*

##### *Market surveillance and control of products entering the Union market*

1. Member States shall organise and perform surveillance of the products that are placed on the Union market in accordance with paragraph 3 of Article 15 and Articles 16 to 26 of Regulation (EC) No 765/2008.
2. Member States shall organise and perform control of the products that enter the Union market in accordance with paragraph 5 of Article 15 and Articles 27, 28 and 29 of Regulation (EC) No 765/2008.
3. Member States shall ensure that their market surveillance and border control authorities cooperate with the competent authorities designated under Article 17 of Regulation (EU) .../... [IR] on safety matters and shall establish appropriate communication and coordination mechanisms between them, making the best use of the information contained in the occurrence reporting system defined in Regulation (EU) No 376/2014 of the European Parliament and of the Council<sup>14</sup> and the information systems defined in Articles 22 and 23 of Regulation (EC) No 765/2008.

#### *Article 36*

##### *Procedure for dealing with products presenting a risk at national level*

1. Where the market surveillance authorities of one Member State have taken action pursuant to Article 20 of Regulation (EC) No 765/2008, or where they have sufficient reason to believe that a product presents a risk to the health or safety of persons or to other aspects of public interest protection covered by this Chapter, they shall carry out an evaluation in relation to the product concerned, covering all applicable requirements laid down in this Chapter. The relevant economic operators shall cooperate as necessary with the market surveillance authorities for that purpose.

Where, in the course of the evaluation referred to in the first subparagraph, the market surveillance authorities find that the product does not comply with the requirements laid down in this Chapter, they shall, without delay, require the relevant economic operator to take all appropriate corrective actions to bring the product into compliance with those requirements, to withdraw the product from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as they may prescribe.

The market surveillance authorities shall inform the relevant notified body accordingly.

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<sup>14</sup> Regulation (EU) No 376/2014 of the European Parliament and of the Council of 3 April 2014 on the reporting, analysis and follow-up of occurrences in civil aviation, amending Regulation (EU) No 996/2010 of the European Parliament and of the Council and repealing Directive 2003/42/EC of the European Parliament and of the Council and Commission Regulations (EC) No 1321/2007 and (EC) No 1330/2007 (OJ L 122, 24.4.2014, p. 18).

Article 21 of Regulation (EC) No 765/2008 shall apply to the measures referred to in the second subparagraph of this paragraph.

2. Where the market surveillance authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.
3. The economic operator shall ensure that all appropriate corrective action is taken in respect of all products concerned that it has made available on the market throughout the Union.
4. Where the relevant economic operator does not take adequate corrective action within the period referred to in the second subparagraph of paragraph 1, the market surveillance authorities shall take all appropriate provisional measures to prohibit or restrict the product being made available on their national market, to withdraw the product from that market or to recall it.  
The market surveillance authorities shall inform the Commission and the other Member States, without delay, of those measures.
5. The information referred to in paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant product, the origin of the product, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to either of the following:
  - (a) failure of the product to meet the requirements set out in Article 4;
  - (b) shortcomings in the harmonised standards referred to in Article 12.
6. Member States other than the Member State initiating the procedure under this Article shall, without delay, inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the product concerned, and, in the event of disagreement with the adopted national measure, of their objections.
7. Where, within three months of receipt of the information referred to in paragraph 5, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.
8. Member States shall ensure that appropriate restrictive measures, such as withdrawal of the product from the market, are taken in respect of the product concerned without delay.

#### *Article 37*

##### *Union safeguard procedure*

1. Where, on completion of the procedure set out in paragraphs 3 and 4 of Article 36, objections are raised against a measure taken by a Member State, or where the Commission considers a national measure to be contrary to Union legislation, the Commission shall, without delay, enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measure.

On the basis of the results of that evaluation, the Commission shall decide whether the national measure is justified or not.

The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

2. If the national measure is considered justified, all Member States shall take the necessary measures to ensure that the non-compliant product is withdrawn or recalled from their market, and shall inform the Commission accordingly. If the national measure is considered unjustified, the Member State concerned shall withdraw that measure.
3. Where the national measure is considered justified and the non-compliance of the product is attributed to shortcomings in the harmonised standards referred to in point (b) of paragraph 5 of Article 36 of this Regulation, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.

#### *Article 38*

##### *Compliant product which presents a risk*

1. Where, having carried out an evaluation under paragraph 1 of Article 36, a Member State finds that, although the product is in compliance with this Chapter, it presents a risk to the health or safety of persons or to other aspects of public interest protection covered by this Chapter, it shall require the relevant economic operator to take all appropriate measures to ensure that the product concerned, when placed on the market, no longer presents that risk, to withdraw the product from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.
2. The economic operator shall ensure that corrective action is taken in respect of all the products concerned that he has made available on the market throughout the Union.
3. The Member State shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the product concerned, the origin and the supply chain of product, the nature of the risk involved and the nature and duration of the national measures taken.
4. The Commission shall, without delay, enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall decide whether the national measure is justified or not and, where necessary, propose appropriate measures.
5. The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

#### *Article 39*

##### *Formal non-compliance*

1. Without prejudice to Article 36, where a Member State makes one of the following findings concerning products covered by this Chapter, it shall require the relevant economic operator to put an end to the non-compliance concerned:

- (a) the CE marking has been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of Article 15 or Article 16 of this Regulation;
  - (b) the CE marking or type has not been affixed;
  - (c) the identification number of the notified body, where the conformity assessment procedure set out in Part 9 of the Annex is applied, has been affixed in violation of Article 16 or has not been affixed;
  - (d) the UA class identification label has not been affixed;
  - (e) the indication of the sound power level if required has not been affixed;
  - (f) the serial number has not been affixed or has not the correct format;
  - (g) the manual or the information notice is not available;
  - (h) the EU declaration of conformity is missing or has not been drawn up;
  - (i) the EU declaration of conformity has not been drawn up correctly;
  - (j) technical documentation is either not available or not complete;
  - (k) manufacturer's or importer's name, registered trade name or registered trademark, website address or postal address are missing.
2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the product being made available on the market or ensure that it is withdrawn or recalled from the market.

## **CHAPTER III**

### **UAS operated in the ‘certified’ and ‘specific’ categories**

#### Article 40

##### *Requirements for UAS operated in the ‘certified’ and ‘specific’ categories*

1. The design, production and maintenance of UAS shall be certified if the UAS meets any of the following conditions:
- (a) it has a characteristic dimension of 3 m or more, and is designed to be operated over assemblies of people;
  - (b) it is designed for transporting people;
  - (c) it is designed for the purpose of transporting dangerous goods and requiring a high level of robustness to mitigate the risks for third parties in case of accident;
  - (d) it is used in the ‘specific’ category of operations defined in Article 5 of Regulation (EU) ...../... [IR] and the operational authorisation issued by the competent authority, following a risk assessment provided for in Article 11 of Regulation (EU) ...../... [IR], considers that the risk of the operation cannot be adequately mitigated without the certification of the UAS.
2. A UAS subject to certification shall comply with the applicable requirements set out in Commission Regulation (EU) No 748/2012, Commission Regulation (EU) No 640/2015 and Commission Regulation (EU) No 1321/2014.

3. Unless it needs to be certified in accordance with paragraph 1, a UAS used in the ‘specific’ category shall feature the technical capabilities set out in the operational authorisation issued by the competent authority or in the standard scenario defined in Appendix 1 to the Annex of Regulation (EU) ...../... [IR] or as defined by the Light UAS Operator Certificate (LUC) pursuant to Part C of the Annex of Regulation (EU) ...../... [IR].

## **CHAPTER IV**

### **Third-country UAS operators**

#### *Article 41*

#### *Third-country UAS operators*

1. UAS operators that have their principal place of business, are established, or reside in a third country, shall comply with Regulation (EU) .../... [IR] for the purpose of UAS operations within the single European sky airspace.
2. The competent authority for the third-country UAS operator shall be the competent authority of the first Member State where the UAS operator intends to operate.
3. By way of derogation from paragraph 1, a certificate of the remote pilot competency or UAS operator in accordance with Regulation (EU) .../... [IR], or an equivalent document, may be recognised by the competent authority for the purpose of operation within, to, and out of the Union provided that:
  - (a) the third country asked for such recognition;
  - (b) the certificate of the remote pilot competency or the UAS operator’s certificate are valid documents of the State of issue; and
  - (c) the Commission, after consultation of EASA, has ensured that the requirements on the basis of which such certificates have been issued provide the same level of safety as this Regulation does.

## **CHAPTER V**

### **Final provisions**

#### *Article 42*

#### *Entry into force*

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

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 12.3.2019

*For the Commission*  
*The President*  
*Jean-Claude JUNCKER*