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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	16 April 2025
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2025) 2258 final
Subject:	COMMISSION DELEGATED REGULATION (EU) …/... of 16.4.2025 amending Delegated Regulation (EU) 2023/2197 as regards the date of application

Delegations will find attached document C(2025) 2258 final.

Encl.: C(2025) 2258 final

EUROPEAN
COMMISSION

Brussels, 16.4.2025
C(2025) 2258 final

COMMISSION DELEGATED REGULATION (EU) …/...

of 16.4.2025

amending Delegated Regulation (EU) 2023/2197 as regards the date of application

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

In April 2017, the European Parliament and the Council adopted Regulation (EU) 2017/745 on medical devices[1] ('the MDR') aiming to introduce a new robust, transparent, predictable and sustainable regulatory framework for medical devices, which ensures a high level of safety, health and innovation.

One of the main changes from the previous Directives[2] is the introduction of the Unique Device Identification ('UDI') system referred to in Article 27 of the MDR, aiming to ensure an adequate level of traceability with respect to medical devices. Basic UDI device identifiers ('Basic UDI-DIs'), UDI-DIs and UDI production identifier ('UDI-PIs') shall be assigned (in compliance with the rules of the designated EU issuing entities[3]) by manufacturers to all devices, other than custom-made devices, prior to the placement on the market. To further strengthen and enhance traceability and recording of UDIs, manufacturers shall report Basic UDI-DIs and UDI-DIs in the European Database on Medical Devices ('Eudamed')[4].

UDI-DI is defined in Part C of Annex VI to the MDR as the identifier specific to a manufacturer and a device. Experience gained through the setting up and implementation of the UDI system in the EU and in other jurisdictions internationally shows that certain devices present a high level of individualisation ('highly individualised devices'), resulting in a disproportionate level of granularity and amount of UDI-DIs which would need to be reported in UDI databases e.g. Eudamed in the EU. In comparison with other medical devices, the numerous possible design (clinical and non-clinical) parameter combinations cause a level of granularity not really needed for regulatory purposes.

The MDR does not provide for the possibility to grant an exemption from registration in Eudamed in the EU for this kind of products. Therefore, in order to resolve the implementation issue and allow for proportionate UDI-DI data entries in Eudamed, and taking into account that the concept of a UDI-DI grouping several devices is already present in the MDR with respect to systems and procedure packs, configurable devices and device software[5], the Commission developed the concept of 'Master UDI-DI', in close collaboration with regulators and relevant stakeholders, including industry, product experts and EU issuing entities. Master UDI-DI is intended as the identifier of a group of highly individualised

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1 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1, ELI: http://data.europa.eu/eli/reg/2017/745/2024-07-09).

2 Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, and Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

3 See Commission Implementing Decision (EU) 2019/939 of 6 June 2019 designating issuing entities designated to operate a system for the assignment of Unique Device Identifiers (UDIs) in the field of medical devices (OJ L 149, 7.6.2019, p. 73, ELI: http://data.europa.eu/eli/dec_impl/2019/939/oj) and Commission Implementing Decision (EU) 2024/2120 of 30 July 2024 renewing the designation of issuing entities designated to operate a system for the assignment of Unique Device Identifiers (UDIs) in the field of medical devices (OJ L, 2024/2120, 1.8.2024, ELI: http://data.europa.eu/eli/dec_impl/2024/2120/oj).

4 See Article 29 of the MDR.

5 Section 6 of Part C of Annex VI to the MDR, in particular Subsections 6.3., 6.4. and 6.5.

devices presenting specific similarities with respect to defined design (clinically and non-clinically) relevant parameters. This is the case of contact lenses, among other products.

The Master UDI-DI solution was introduced in the MDR for contact lenses by Commission Delegated Regulation (EU) 2023/2197[6], adding, in Section 6 of Part C of Annex VI to the MDR, a new Section 6.6. on 'Highly individualised devices' and a Subsection 6.6.1. on 'Contact lenses'. This Regulation, adopted on 10 July 2023 and published in the *Official Journal of the European Union* (OJEU) on 20 October 2023 after the prescribed scrutiny by the European Parliament and the Council, was set to apply from 9 November 2025, two years after its entering into force. This transitional period was considered necessary in the light of the nature and complexity of the subject matter and obligations at stake.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The concerned Subgroup on Unique Device Identification (UDI) of the Medical Device Coordination Group (MDCG) established under Article 103 of Regulation (EU) 2017/745, at their meetings held on 6 March 2023[7], 13 November 2023[8] and 6 March 2024[9], identified the need of an appropriate guidance document endorsed by the MDCG to support the implementation of the Master UDI-DI solution for contact lenses as laid down in Regulation (EU) 2023/2197, to ensure a clear and harmonised approach by all the concerned manufacturers.

Such a guidance document was intended to be delivered shortly after the entering into force of Regulation (EU) 2023/2197, to provide as much time as possible to manufacturers to adequately implement the Master UDI-DI solution for contact lenses and adapt their internal systems and technologies for UDI assignment. However, due to the complexity of the matter as newly introduced and the need to ensure the highest technical accuracy and usefulness of the document for users, together with adequate involvement of Member States and relevant stakeholders, the elaboration of the guidance document took longer than initially foreseen.

After final discussions at the meeting on 29 October 2024[10] of the MDCG UDI Subgroup and their endorsement by written procedure on 7 November 2024, the necessary guidance document MDCG 2024-14 'Guidance on the implementation of the Master UDI-DI solution for contact lenses' was definitively endorsed by the MDCG and published on the Commission website in November 2024[11], so only one year before the date of application of Regulation (EU) 2023/2197.

Taking into account the time between the effective availability of the guidance document and the date of application of the Master UDI-DI solution for contact lenses, limited to only one

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6 Commission Delegated Regulation (EU) 2023/2197 of 10 July 2023 amending Regulation (EU) 2017/745 of the European Parliament and of the Council, as regards the assignment of Unique Device Identifiers for contact lenses (OJ L, 2023/2197, 20.10.2023, ELI: http://data.europa.eu/eli/reg_del/2023/2197/oj).

7 See https://ec.europa.eu/transparency/expert-groups-register/screen/meetings/consult?lang=en&meetingId=46707.

8 See https://ec.europa.eu/transparency/expert-groups-register/screen/meetings/consult?lang=en&meetingId=50216.

9 See https://ec.europa.eu/transparency/expert-groups-register/screen/meetings/consult?lang=en&meetingId=52000.

10 See https://ec.europa.eu/transparency/expert-groups-register/screen/meetings/consult?lang=en&meetingId=54339.

11 See https://health.ec.europa.eu/document/download/c8c6cca5-460e-410e-a325-be08bfc7dea6_en?filename=mdcg_2024-14_en.pdf.

year instead of the two years initially established, it is convenient to amend Regulation (EU) 2023/2197 by deferring the date of its application by one year, until 9 November 2026. This is key to take into due consideration the technical nature and complexity of the subject and the legal obligations in questions, as well as to give more time to operators to plan implementation efforts and resource allocation, and to ensure the necessary level of legal certainty on the market and a smooth transition to the new rules. During the transitional phase, Eudamed will be able to accommodate the implementation of the Master UDI-DI solution for contact lenses on a voluntary basis.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The delegated Regulation is a Delegated measure adopted pursuant to Article 27(10)(b) of the MDR whereby the Commission is empowered to amend Annex VI to the MDR in light of international developments and technical progress in the field of Unique Device Identification.

COMMISSION DELEGATED REGULATION (EU) …/...

of 16.4.2025

amending Delegated Regulation (EU) 2023/2197 as regards the date of application

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC[1], in particular Article 27(10), point (b), thereof,

Whereas:

(1) Commission Delegated Regulation (EU) 2023/2197[2] amended Regulation (EU) 2017/745 as regards the assignment of Unique Device Identifiers (UDI) for contact lenses as highly individualised devices, by introducing the 'Master UDI-DI' solution. Delegated Regulation (EU) 2023/2197 is to apply from 9 November 2025.

(2) The Subgroup on Unique Device Identification of the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745 identified a need to develop guidance to ensure effective and harmonised implementation of the Master UDI-DI solution for contact lenses.

(3) The MDCG endorsed guidance document MDCG 2024-1 'Guidance on the implementation of the Master UDI-DI solution for contact lenses'. The Commission published that guidance document on its website in November 2024[3], one year before the date of application of Delegated Regulation (EU) 2023/2197.

(4) Given the clear need for availability of that guidance document for operators to plan their implementation efforts and resource allocation on such complex technical matter, in order to allow them to adequately implement the Master UDI-DI solution for contact lenses and adapt their internal systems and technologies for UDI assignment, as well as to ensure the necessary level of legal certainty on the market and a smooth transition to the new rules, it is appropriate to defer the date of application of Delegated Regulation (EU) 2023/2197 by one year.

(5) Delegated Regulation (EU) 2023/2197 should therefore be amended accordingly,

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1 OJ L 117, 5.5.2017, p. 1, ELI: http://data.europa.eu/eli/reg/2017/745/oj.

2 Commission Delegated Regulation (EU) 2023/2197 of 10 July 2023 amending Regulation (EU) 2017/745 of the European Parliament and of the Council, as regards the assignment of Unique Device Identifiers for contact lenses (OJ L, 2023/2197, 20.10.2023, ELI: http://data.europa.eu/eli/reg_del/2023/2197/oj).

3 https://health.ec.europa.eu/document/download/c8c6cca5-460e-410e-a325-be08bfc7dea6_en?filename=mdcg_2024-14_en.pdf.

HAS ADOPTED THIS REGULATION:

Article 1

In Delegated Regulation (EU) 2023/2197, Article 2, the second paragraph is replaced by the following:

‘It shall apply from 9 November 2026.’

Article 2

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, 16.4.2025

For the Commission
The President
Ursula VON DER LEYEN