EUROPEAN
COMMISSION

Brussels, XXX
[…](2025) XXX draft

COMMISSION DELEGATED REGULATION (EU) …/...

of XXX

amending Regulation (EU) 2017/745 of the European Parliament and of the Council, as regards the assignment of Unique Device Identifiers for spectacle frames, spectacle lenses and ready-to-wear reading spectacles

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

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 ('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 their 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 an extremely high level of granularity not really needed for regulatory purposes.

Current examples of highly individualised devices are contact lenses, spectacle frames, spectacle lenses and ready-to-wear reading spectacles[5].

Therefore, in order to resolve the implementation issue and allow for proportionate UDI-DI data entries in Eudamed, the concept of 'Master UDI-DI' has been developed by the Commission 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 devices (i.e.

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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 As per 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). Designations have been extended as per 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 As per Article 29 of the MDR.

5 Also called "ready-made reading spectacles" or "ready readers".

contact lenses, spectacle frames, spectacle lenses and ready-to-wear reading spectacles) presenting specific similarities with respect to defined design (clinically and non-clinically) relevant parameters.

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[6]. The Master UDI-DI concept was introduced in the MDR for contact lenses by Commission Delegated Regulation (EU) 2023/2197[7], adding, in Section 6 of Part C of Annex VI to the MDR, a new Section 6.6. on 'Highly individualised services' and a Subsection 6.6.1. on 'Contact lenses'.

As announced in the Explanatory Memorandum of the Commission Proposal for that act for contact lenses, the Master UDI-DI concept could be extended to other highly individualised devices: this is now the case of spectacle frames, spectacle lenses and ready-to-wear reading spectacles. Should the need arise, the Commission will propose new delegated acts to further extend the Master UDI-DI concept to other devices.

Therefore, the Commission proposes, through a delegated act to be adopted pursuant to Article 27(10)(b) of the MDR, a new amendment to Section 6 of Part C of Annex VI to the MDR, adding a Subsection 6.6.2. on 'Spectacle frames, spectacle lenses and ready-to-wear reading spectacles', in order to adapt the UDI-DI assignment criteria to such kind of devices, within the Master UDI-DI concept.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

Implementation of the UDI system by industry in the EU began in 2012 on a voluntary basis, jointly with other international regulators at the level of the International Medical Device Regulators Forum (IMDRF)[8]. The IMDRF UDI Working Group (WG) was chaired by the EU. Following the adoption of the MDR, the Commission UDI expert group was established in 2019, which is a subgroup of the Medical Devices Coordination Group (MDCG)[9], although its predecessor under the Directives was also active prior to that time.

In order to discuss the implementation issue with regards to assignment of UDI-DIs to spectacle frames, spectacle lenses and ready-to-wear reading spectacles, following the work already carried out on contact lenses, a number of meetings with relevant stakeholders took place (2022-2024), including with relevant business associations for eyewear products including contact lenses, spectacle frames, spectacle lenses and ready-to-wear reading spectacles.

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

7 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). It entered into force on 9 November 2023 and will be applicable two years later, on 9 November 2025, even if manufacturers may already before that date assign a Master UDI-DI in accordance with the MDR as amended.

8 https://www.imdrf.org.

9 Medical Device Coordination Group (X03565) https://ec.europa.eu/transparency/expert-groups-register/screen/expert-groups/consult?lang=en&groupID=3565, as per Article 103 of the MDR.

In the MDCG UDI Subgroup (Working Group 9), which includes representatives of competent authorities of the Member States and of organisations of economic operators, patients and users of medical devices, a series of workshops and other consultations, communication and exchange activities on the Master UDI-DI concept with regulators and stakeholders took place since 2020. Views, opinions and proposals from stakeholders were analysed by regulators and the Commission, and in 2021 the MDCG UDI Subgroup agreed to proceed with the implementation of the Master UDI-DI concept for different types of devices, starting with contact lenses. Following the agreement reached at the level of the MDCG UDI Subgroup, the Commission submitted a request to the EU issuing entities in order to start the work for the implementation of the proposed solution. In the MDCG UDI Subgroup meeting held in November 2023, it was decided to extend the Master UDI-DI concept also to spectacle frames, spectacle lenses and ready-to-wear reading spectacles.

In a similar way as done for the preparation of the delegated act on contact lenses, this draft Delegated Regulation on spectacle frames, spectacle lenses and ready-to-wear reading spectacles is going to be open for feedback during 4 weeks on the "Have Your Say" platform https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14414-Medical-devices-spectacle-frames-lenses-and-ready-made-reading-glasses-unique-identifiers-_en.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The proposed 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. In order to resolve the implementation issue concerning the registration of UDI-DI data elements in Eudamed for spectacle frames, the Commission is empowered to establish a specific UDI-DI assignment rule for such devices. This solution will allow for a more effective implementation of the UDI system at Union level for spectacle frames, spectacle lenses and ready-to-wear reading spectacles as already done with contact lenses.

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amending Regulation (EU) 2017/745 of the European Parliament and of the Council, as regards the assignment of Unique Device Identifiers for spectacle frames, spectacle lenses and ready-to-wear reading spectacles

(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) Regulation (EU) 2017/745 provides for a Unique Device Identification (UDI) system for the identification and traceability of devices. Before placing a device, other than a custom-made device, on the market, the manufacturer is required to assign to the device and to all higher levels of packaging of the device, a UDI. The UDI comprises of a device identifier (UDI-DI) and a production identifier (UDI-PI). The UDI-DI is one of the core elements which a manufacturer needs to provide to the UDI database in the European database on medical devices ('Eudamed').

(2) A UDI-DI is assigned to a specific model of device and manufacturer. Spectacle frames, spectacle lenses and ready-to-wear reading spectacles, also called ready-made reading spectacles or ready readers, are available in many variants due to the high number of design (clinical and non-clinical) parameters and construction variants that characterise them. As a result an UDI-DI is assigned to each such variant. This individualisation at UDI-DI level results in a proliferation of UDI-DIs to be assigned to similar spectacle frames, spectacle lenses and ready-to-wear reading spectacles and a disproportionate number of UDI-DI data entries in Eudamed relative to the safety risk associated with these products.

(3) Developments at international level and discussions with issuing entities, industry and other relevant stakeholders, and Union competent authorities for medical devices, together with the technical progress, suggest that certain highly individualised devices such as spectacle frames, spectacle lenses and ready-to-wear reading spectacles that have the same design (clinical and non-clinical) parameter combinations are more appropriately grouped under the same UDI-DI ('Master UDI-DI'). In order to avoid assignment of different device identifiers to very similar spectacle frames, spectacle lenses and ready-to-wear reading spectacles, a solution is therefore needed for UDI-DI assignment to these products.

[1] OJ L 117, 5.5.2017, p. 1, ELI: http://data.europa.eu/eli/reg/2017/745/2024-07-09.

(4) Regulation (EU) 2017/745 should therefore be amended accordingly.

(5) In order to comply with the amendments made by this Regulation economic operators must implement changes in their internal systems and adapt technologies for printing and scanning UDI carriers. The application of this Regulation should therefore be deferred,

HAS ADOPTED THIS REGULATION:

Article 1

In Part C of Annex VI to Regulation (EU) 2017/745 the following sections are added:

‘6.6.2. Spectacle frames, spectacle lenses and ready-to-wear reading spectacles

6.6.2.1. Spectacle frames

A UDI-DI shall be assigned to spectacle frames that have the same combination of design parameters, including at least the horizontal boxed lens size (‘Master UDI-DI’).

In addition to the requirement laid down in Section 3.9, a new Master UDI-DI shall be required whenever there is a change in the combination of the design parameters referred to in the first paragraph.

6.6.2.2. Spectacle lenses

A UDI-DI shall be assigned to spectacle lenses that have the same combination of design parameters, including at least groups of mean sphere (spherical equivalent power), groups of addition power and groups of similar vision impairments (‘Master UDI-DI’).

In addition to the requirement laid down in Section 3.9, a new Master UDI-DI shall be required whenever there is a change in the combination of the design parameters referred to in the first paragraph.

6.6.2.3. Ready-to-wear reading spectacles

A UDI-DI shall be assigned to ready-to-wear reading spectacles that have the same combination of design parameters, including at least the horizontal boxed lens size and lens spherical power (‘Master UDI-DI’).

In addition to the requirement laid down in Section 3.9, a new Master UDI-DI shall be required whenever there is a change in the combination of the design parameters referred to in the first paragraph.’.

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*.

It shall apply from *[date = first day of the month following 3 years after the date of entry into force of this Regulation]*.

However, manufacturers may already before that date assign a Master UDI-DI in accordance with Regulation (EU) 2017/745 as amended by this Regulation.

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

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN