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COMMISSION DELEGATED REGULATION (EU) …/...

of 10.7.2023

amending Regulation (EU) 2017/745 of the European Parliament and of the Council, as regards the assignment of Unique Device Identifiers for contact lenses

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

In April 2017, the European Parliament and the Council adopted Regulations (EU) 2017/745 on medical devices (MDR)[1], 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 MDR, aiming to ensure an adequate level of traceability with respect to medical devices and in vitro diagnostic medical devices. Basic UDI-DIs, UDI-DIs and 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 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 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 clinical parameter combinations cause a level of granularity not needed for regulatory purposes.

A current example of highly individualised devices concerned is contact lenses, which has been the focus of the discussions both at EU and international level.

Other jurisdictions that implement a UDI system are faced with the same implementation problem with respect to contact lenses but have the possibility to grant an exemption to manufacturers of those highly individualised devices, to not report the UDI-DIs entries in their UDI Databases.

The MDR does not provide for the possibility to grant such an exemption in the EU. Therefore, in order to resolve the implementation issue and allow for proportionate UDI-DI data entries in Eudamed, the "Master UDI-DI" has been developed by the Commission in close collaboration with regulators and relevant stakeholders, including industry, contact lenses experts and EU issuing entities. Master UDI-DI is intended as the identifier of a group of highly individualised devices (i. e. contact lenses) presenting specific similarities with respect to defined clinically relevant

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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.)

2 Directive 98/79/EC of the European Parliament and of the Council on *In Vitro* Diagnostic Medical Devices, Council Directive 93/42/EEC on Medical Devices, Council Directive 90/385/EEC on Active Implantable Medical Devices.

3 Entities designated to operate a system for the assignment of Unique Device Identifiers (UDIs) in the field of medical devices as per Commission Implementing Decision (EU) 2019/939 of 6 June 2019.

4 As per Article 29 of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

parameters. Whilst in the future the Master UDI-DI solution could be extended to other highly individualised devices, at present the focus remains on contact lenses. Should the need arise, the Commission will propose a new delegated act to extend the Master UDI-DI solution to other devices.

The concept of a UDI-DI grouping several devices is already present in the MDR, with respect to system and procedure packs, configurable devices and software[5]. Therefore, the Commission proposes, through a delegated act to be adopted pursuant to Article 27 (10) (b) MDR, an amendment to Part C of Annex VI to Regulation (EU) 2017/745, adding a section concerning 'highly individualised devices' and specifically contact lenses, in order to adapt the UDI-DI assignment criteria to such kind of devices and introducing 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). 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)[6], 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 contact lenses, a number of meetings with relevant stakeholders took place (2019-2022), in particular with relevant associations for eyewear products including contact lenses, spectacle frames and ready readers.

Moreover, meetings with the EU UDI issuing entities on the subject matter took place during the course of 2019-2022 in order to analyse, identify and develop possible new solutions to enable technical progress in the field of Unique Device identification.

The EU also discussed the identified issues for UDI implementation with global partners and other international Regulators.

In the MDCG UDI subgroup, a series of workshops with regulators and stakeholders took place in 2020. 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" solution.

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.

This draft Delegated Regulation has also undergone the 4-week public feedback period under the Better Regulation framework. The feedback received mainly focused on the proposal for clinical sizes to be included as additional production identifiers of contact lenses (UDI-PI) for which concerns were raised as regards the enlargement of the barcodes and the fact that the potential benefit did not outweigh

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5 Annex VI to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, points 6.3 on System and procedure packs, 6.4 on configurable devices and 6.5 on Software.

6 As per Article 103 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices. (n. X03565) - Terms of reference.

the burden of implementation. The feedback received has been reflected in this Delegated Regulation by removing the provision on clinical sizes to be included as additional production identifiers of contact lenses.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The proposed Regulation is a Delegated measure adopted pursuant to Article 27 (10) (b) of Regulation (EU) 2017/745 whereby the Commission is empowered to amend Annex VI of that Regulation 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 contact lenses, 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.

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(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 to assign to the device and to all higher levels of packaging of the device a UDI. The UDI comprises 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 to be assigned to a specific model of device and manufacturer. Contact lenses are available in many variants due to the high number of clinical parameters that characterise them. In accordance with Regulation (EU) 2017/745, an UDI-DI is to be assigned to each of such variants of contact lenses. This individualisation at UDI-DI level, that results in a proliferation of UDI-DIs to be assigned to similar contact lenses, overwhelms Eudamed and is disproportionate compared to the safety risk associated with contact lenses.

(3) Taking into account progress at international level and collaboration with issuing entities, concerned industry stakeholders and Union competent authorities for medical devices, the technical development in this field is such that contact lenses that have the same clinical and design 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 contact lenses, a solution is therefore needed for UDI-DI assignment to contact lenses.

(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

[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.)

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. Highly individualised devices

6.6.1 Contact lenses

6.6.1.1 Standard contact lenses

A UDI-DI shall be assigned to standard contact lenses that have the same combination of contact lens design parameters, including at least base curve and diameter (‘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.

6.6.1.2 Made to order contact lenses

A UDI-DI shall be assigned to made to order contact lenses that have the same combination of contact lens design parameters, including at least base curve and diameter (‘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 = 2 years from 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, 10.7.2023

For the Commission
The President
Ursula VON DER LEYEN