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COMMISSION DELEGATED REGULATION (EU) 2025/1920

of 12 June 2025

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.

(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,

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

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 1 November 2028.

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, 12 June 2025.

For the Commission
The President
Ursula VON DER LEYEN