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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

(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 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

([1]) OJ L 117, 5.5.2017, p. 1.

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 9 November 2025.

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 July 2023.

For the Commission
The President
Ursula VON DER LEYEN