

## **MDCG 2021-09**

# **MDCG Position Paper on the Implementation of UDI requirements for contact lenses, spectacle frames, spectacle lenses & ready readers**

**May 2021**

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and a representative of the European Commission chairs it.

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Article 27 of Regulation (EU) 2017/745 on Medical Devices (MDR) introduces a Unique Device Identification (UDI) system, which among other functions aims to improve the identification of devices and enhance the effectiveness of post-market safety-related activities for devices. In the interest of proportional data-entries in EUDAMED for certain highly individualised products, specific UDI assignment solutions are envisaged. As such, this position paper is intended to provide clarification on the Implementation of UDI requirements from 26 May 2021, for contact lenses, spectacle frames, spectacle lenses & ready readers until solutions are finalised. This Position Paper should be read in conjunction with the relevant provisions of Regulations (EU) 2017/745 (notably Chapter III and Annex VI) and related UDI guidance documents.

Article 10 (7) MDR mandates that manufacturers shall comply with the obligations relating to the UDI system referred to in Article 27 and with the registration obligations referred to in Articles 29 and 31 of the MDR.

Article 27(3) MDR mandates that before placing a device, other than a custom-made device, on the market, the manufacturer shall assign to the device and, if applicable, to all higher levels of packaging, a UDI. In addition, Article 29(3) sets out the obligation for the manufacturers to assign a Basic UDI-DI as defined in Part C of Annex VI to the device.

Article 27(4) MDR mandates that UDI carriers shall be placed on the label of the device and on all higher levels of packaging. This obligation applies for implantable devices and for class III devices from 26 May 2021, for class IIa and class IIb devices from 26 May 2023 and for class I devices from 26 May 2025 in accordance with Article 123 (f) MDR.

Finally, Article 29(1) MDR mandates that Basic UDI-DI, together with the other core data elements referred to in Part B of Annex VI related to that device shall be provided

to the UDI database. As clarified under Article 123(3)(e) MDR however, Article 29(4) MDR on the registration of devices starts to apply 24 months after the date of publication of the notice referred to in Article 34(3) MDR.

In light of the above, and considering that:

(a) for contact lenses, a specific UDI assignment solution is under development by the MDCG UDI WG, which may also be extended to spectacle frames and

(b) for spectacle lenses and ready readers, whilst a specific UDI assignment solution is agreed,<sup>1</sup> its practical application is yet to be formalised

the following clarifications should be observed in terms of UDI assignment, carrier labelling and registration.

**UDI Assignment:** the abovementioned products are expected to be in compliance with the UDI assignment obligations set out in Art 27(3) and Art 29 (1) MDR, applying mandatorily from 26 May 2021, until specific UDI assignment solutions are finalised.

**UDI Carrier Labelling:** for Implantable devices and Class III devices, Class IIa/IIb devices and Class I devices, UDI labelling requirements apply from May 2021, May 2023, and May 2025 respectively. As the majority of the aforementioned products are Class IIa/IIb devices and Class I devices, it is expected that there will be sufficient time to reflect the specific UDI assignment solutions on the label.

**UDI & Device Registration:** registration of devices starts to apply 24 months after the date of publication of the notice referred to in Article 34(3) MDR. Before this time, or until specific UDI assignment solutions are finalised, manufacturers of the abovementioned products are instructed not to use on a voluntary basis, the UDI/Device registration module of EUDAMED, to register devices and UDI related information as established in Part A and B of Annex VI MDR.

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<sup>1</sup> Please see [‘MDCG Position Paper on UDI assignment for Spectacle lenses & Ready readers’](#)