MDCG 2025-7

MDCG Position Paper:

Timelines of the implementation of ‘Master UDI-DI’ to contact lenses and spectacle frames, spectacle lenses and ready-to-wear reading spectacles

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 it is chaired by a representative of the European Commission.

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Background

The introduction of the **Unique Device Identification (UDI)** system referred to in Article 27 of Regulation (EU) 2017/745 on medical devices[1] ('the MDR') aims to ensure an adequate level of identification and traceability of medical devices. Basic UDI-DIs, UDI-DIs and UDI-PIs shall be assigned (in compliance with the rules of the designated issuing entities) 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 register Basic UDI-DIs and UDI-DIs in UDI/Device registration module[2] of the **European Database on Medical Devices (Eudamed)**[3].

For devices presenting a high level of individualisation ('highly individualised devices'), notably **contact lenses** and **spectacle frames, spectacle lenses and ready-to-wear reading spectacles**, and in order to adapt the UDI-DI assignment criteria to such kind of devices, the assignment of a '**Master UDI-DI**' has been foreseen according to Annex VI, Part C, Sections 6.6.1 and 6.6.2 of the MDR, as amended by Commission Delegated Regulation (EU) 2023/2197 on Master UDI-DI for contact lenses[4] and by Commission Delegated Regulation (EU) …/… on Master UDI-DI for spectacle frames, spectacle lenses and ready-to-wear reading spectacles[5]. The Master UDI-DI technical solution aims to group highly individualised devices with specific similarities in terms of relevant design parameters under a common identifier to be assigned and registered in the UDI/Device registration module of Eudamed, thus relieving manufacturers, distributors and the Eudamed database from having too many identifiers assigned for similar devices. The Master UDI-DI technical solution for such devices is being developed by the EU UDI issuing entities[6].

According to MDCG 2021-24 Guidance on classification of medical devices[7], corrective contact lenses are considered to be class IIa (short-term use) or class IIb (long-term use) medical devices. Spectacle frames (i.e. glasses), spectacle lenses and ready-to-wear reading spectacles are considered to be class I medical devices.

This MDCG Position Paper aims at clarifying the timelines of the implementation of the Master UDI-DI to the abovementioned devices, as established in the respective Delegated Regulations, and the obligation to label the Master UDI-DI and to use the UDI/Device registration module of Eudamed, and the interrelation between them.

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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. Current consolidated version ELI: https://eur-lex.europa.eu/eli/reg/2017/745/2025-01-10).

[2] https://health.ec.europa.eu/medical-devices-eudamed/udidevice-registration_en.

[3] https://health.ec.europa.eu/medical-devices-eudamed_en.

[4] 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), and Commission Delegated Regulation (EU) …/… of 16 April 2025 amending Delegated Regulation (EU) 2023/2197 as regards the date of application (https://webgate.ec.europa.eu/regdel/#/delegatedActs/2642).

[5] Commission Delegated Regulation (EU) …/… 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 https://webgate.ec.europa.eu/regdel/#/delegatedActs/2596).

[6] https://health.ec.europa.eu/medical-devices-topics-interest/unique-device-identifier-udi_en#udi-issuing-entities.

[7] https://health.ec.europa.eu/document/download/cbb19821-a517-4e13-bf87-fdc6ddd1782e_en?filename=mdcg_2021-24_en.pdf.

Reference dates

- **Application of UDI labelling requirements:**

As established in Article 123(3)(f) of the MDR, the provisions of Article 27(4) on the placement of UDI carriers on the label of the device and on all higher levels of packaging apply for classes IIa and IIb devices from **26 May 2023**, while for class I devices they apply from **26 May 2025**.

- **Mandatory use of the UDI/Device registration module in Eudamed:**

As established in Article 29 and in Article 123 of the MDR, as amended by Regulation (EU) 2024/1860[8], and according to the latest available Eudamed timeline[9], the use of the UDI/Device registration module of Eudamed should become mandatory to use as from **the first quarter (Q1) of 2026**, it is to say, 6 months after the publication in the *Official Journal of the European Union* (OJEU) of the notice confirming the functionality of that module.

- **Implementation of Master UDI-DI to contact lenses:**

As established in Commission Delegated Regulation (EU) 2023/2197 of 10 July 2023, as amended, the Master UDI-DI solution must be implemented by manufacturers of contact lenses as from **9 November 2026**, three years after the entering into force of the act. Contact lenses produced prior to 9 November 2026 are not required to have a Master UDI-DI on the label.

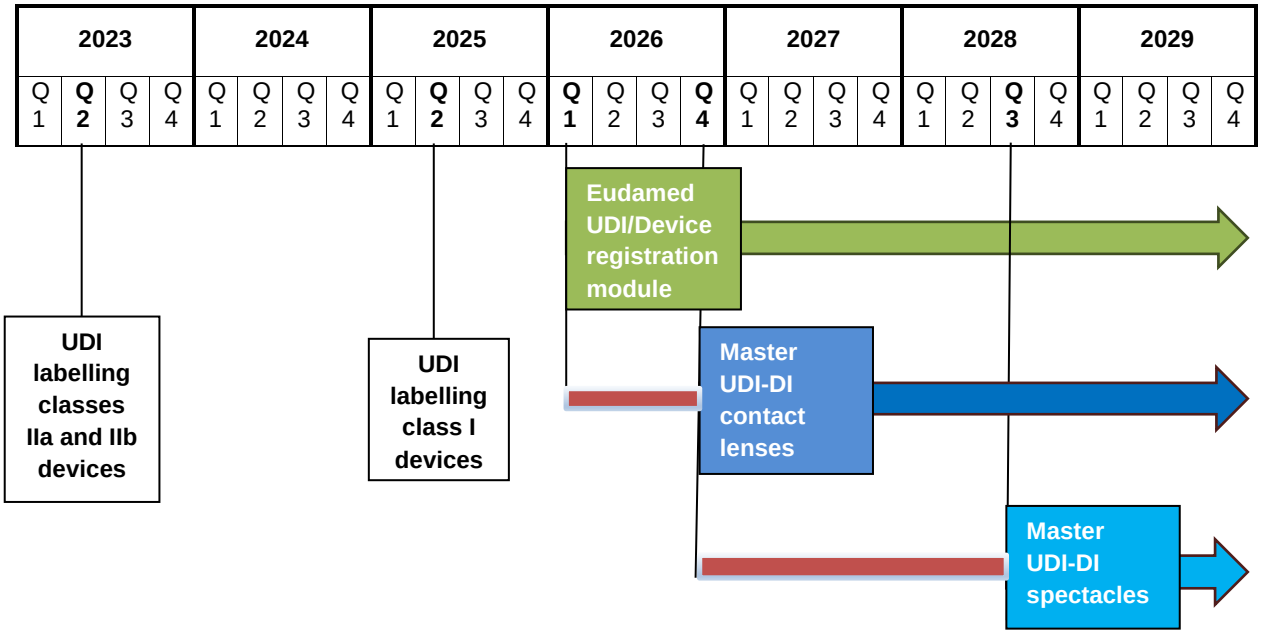
- **Implementation of Master UDI-DI to spectacle frames, spectacle lenses and ready-to-wear reading spectacles:**

As established in Commission Delegated Regulation of 12 June 2025, the Master UDI-DI solution must be implemented by manufacturers of spectacle frames, spectacle lenses and ready-to-wear reading spectacles as from **September 2028**, three years after the entering into force of the act.

The abovementioned dates are represented in the diagram below.

[8] Regulation (EU) 2024/1860 of the European Parliament and of the Council of 13 June 2024 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain *in vitro* diagnostic medical devices (OJ L, 2024/1860, 9.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1860/oj).

[9] https://health.ec.europa.eu/document/download/04ce2012-97df-4dd0-8a39-d4f6993b9e16_en?filename=md_eudamed_roadmap_en.pdf. See also "Q&A on practical aspects related to the implementation of the gradual roll-out of Eudamed pursuant to the MDR and IVDR, as amended by Regulation (EU) 2024/1860" https://health.ec.europa.eu/document/download/0e7327c7-0e06-4fbd-90d3-8ab7bb30fe9f_en?filename=md_mdcg_2024-11_eudamed-qa.pdf.



In red the representation of the time lapses when the use of the UDI/Device registration module in Eudamed is mandatory but not the Master UDI-DI assignation yet:

- for contact lenses: from Q1 2026 to Q4 2026
- for spectacle frames, spectacle lenses and ready-to-wear reading spectacles: from Q1 2026 to Q3 2028

Considerations and way forward

The different and partially overlapping timelines for the assignment, labelling and registration of the 'highly individualised devices' subject to the Master UDI-DI (contact lenses, spectacle frames, spectacle lenses and ready-to-wear reading spectacles) make that the obligation to label the Master UDI-DI and register those devices in the UDI/Device registration module of Eudamed follows the Master UDI-DI assignment obligation, with time laps spanning from about 10 months for contact lenses to about 30 months for spectacle frames, spectacle lenses and ready-to-wear reading spectacles.

However, the relevant Commission Delegated Regulations, in their respective Articles 2 *in fine*, provide for the possibility for manufacturers to voluntarily assign a Master UDI-DI before it becomes mandatory on the respective dates of application. This means that manufacturers should try to assign Master UDI-DIs as soon as possible even before the assignment becomes mandatory, with the obligation to label it and register the devices in Eudamed immediately following, after the assignment is done.

From 26 May 2025 until the Master UDI-DI solution (acting as UDI-DI for high individualised devices) is fully available through the relevant Commission Delegated Regulations and the appropriate EU UDI issuing entity standard, the abovementioned high individualised devices

will continue to be identified with either an issuing entity identifier or similar internal manufacturer device identifier as for the current procedures.

Manufacturers of contact lenses, spectacle frames, spectacle lenses and ready-to-wear reading spectacles are strongly encouraged to make use of the voluntary assignment of Master UDI-DI before the mandatory dates of application in due time, to be able to take advantage of the features offered by the Master UDI-DI solution.

On the other hand, once the Vigilance and post-market surveillance module in Eudamed is mandatory to use[10], Master UDI-DI, if assigned, should be used for reporting of vigilance cases for contact lenses, spectacle frames, spectacle lenses and ready-to-wear reading spectacles even though the application dates of the Commission Delegated Regulations on Master UDI-DI have not passed yet.

More information on the implementation of the Master UDI-DI solution for contact lenses, spectacle frames, spectacle lenses and ready-to-wear reading spectacles is available on the guidance documents MDCG 2024-14[11] and MDCG 2025-XX[12], including the practical handling of reporting of vigilance cases.

[10] Q3 2026 according to the latest available Eudamed timeline https://health.ec.europa.eu/document/download/04ce2012-97df-4dd0-8a39-d4f6993b9e16_en?filename=md_eudamed_roadmap_en.pdf.

[11] MDCG 2024-14 Guidance on the implementation of the Master UDI-DI solution for contact lenses https://health.ec.europa.eu/document/download/c8c6cca5-460e-410e-a325-be08bfc7dea6_en?filename=mdcg_2024-14_en.pdf.

[12] MDCG 2025-XX Guidance on the implementation of the Master UDI-DI solution for spectacle frames, spectacle lenses and ready-to-wear reading spectacles.