MDCG 2024-14

Guidance on the implementation of the Master UDI-DI solution for contact lenses

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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Contents

Introduction and scope

The introduction of the Unique Device Identification (UDI) system referred to in Article 27 of Regulation (EU) 2017/745 on medical devices (MDR)[1] aims to ensure an adequate level of identification and traceability with respect to 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 the European Database on Medical Devices (Eudamed)[2].

For contact lenses, which are devices presenting a high level of individualisation ('highly individualised devices'), the assignment of a Master UDI-DI has been foreseen according to Annex VI, Part C, Section 6.6.1 MDR, as amended by Commission Delegated Regulation (EU) 2023/2197 on Master UDI-DI for contact lenses[3].

Even though all economic operators have to contribute to an appropriate level of traceability according to Article 25 MDR, the main responsibility to apply the means to achieve proper identification and traceability of the device lies with the manufacturer.

This document aims to provide guidance in the implementation of Master UDI-DI rules for contact lenses as regards its structure, assignment, labelling and registration in Eudamed.

NOTE: *this document is intended to be read in conjunction with Regulation (EU) 2017/745 on medical devices (MDR), Commission Delegated Regulation (EU) 2023/2197 and other MDCG Guidance documents on UDI*[4].

[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/2017/745/2024-07-09)

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

[3] 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)

[4] https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en#sec18

1. Terminology[5]

Standard contact lenses (covering both standard soft contact lenses and rigid gas permeable (RGP) contact lenses): mass-produced contact lenses which are generally held in stock by the manufacturer / distributor / eye care professional and have a limited range of parameters. Example: standard soft daily disposable contact lenses.

Made to Order contact lenses (soft or rigid): lenses where (part of) the production process is initiated based on a specific individual order. These typically have a wide range of parameters. Example: lathe cut 3-monthly made-to order lens.

Contact Lens Design Parameters: the contact lens parameters that are used to identify the clinical sizes towards the users, eye care professionals and other concerned stakeholders: e.g. Base Curve, Diameter, Add Power, Axis…

Basic UDI-DI: the primary identifier of a device model, which means the identifier to connect devices with the same intended purpose, risk class and essential design and manufacturing characteristics. For contact lenses the parameters to trigger the assignment of Basic UDI-DI may include for example the material, filters and tint, lens type (spheric/toric/multifocal etc.). It is the main key for records in the UDI database in Eudamed and is referenced in relevant certificates and EU declarations of conformity. Rules for Basic UDI-DI do not change for contact lenses.

Master UDI-DI: the unique identifier used for grouping certain highly individualised devices. Such highly individualised devices present specific similarities with respect to pre-defined clinically relevant parameters (e.g. a single Master UDI-DI should be assigned to contact lenses that have the same combination of contact lens design parameters, including at least base curve and diameter). The Master UDI-DI is the access key to device information related to a group of devices with the same intended purpose and the same principal design, stored in Eudamed. Master UDI-DI assignment should follow the rules of EU designated issuing entities. The Master UDI-DI shall be associated to a Basic UDI-DI, which shall be assigned per the MDR and MDCG 2018-1.

UDI-PI: according to Annex VI, Part C, Section 1 MDR, the different types of UDI-PIs include serial number, lot number, software identification and manufacturing or expiry date or both types of date. The UDI-PI types also apply to contact lenses. The UDI (Master UDI-DI + UDI-PI) intends to enable the automatic identification of the individual device to conform with the UDI requirements in the MDR.

[5] For UDI-related definitions and other terminology, see Part C of Annex VI to the MDR

2. The Master UDI-DI

The hierarchy of assignment of Basic UDI-DI (BUDI) and Master UDI-DI (MUDI) differs from the assignment of UDI-DI. In figure 1 below, each and every sub-box would be assigned a UDI-DI, yielding a huge number of UDI-DIs which is not practicable and would introduce unnecessary complexity with no added value for authorities and economic actors. The assignment of Master UDI-DI on grouped level, corresponding to the second row from the top in figure 1, will be more appropriate.

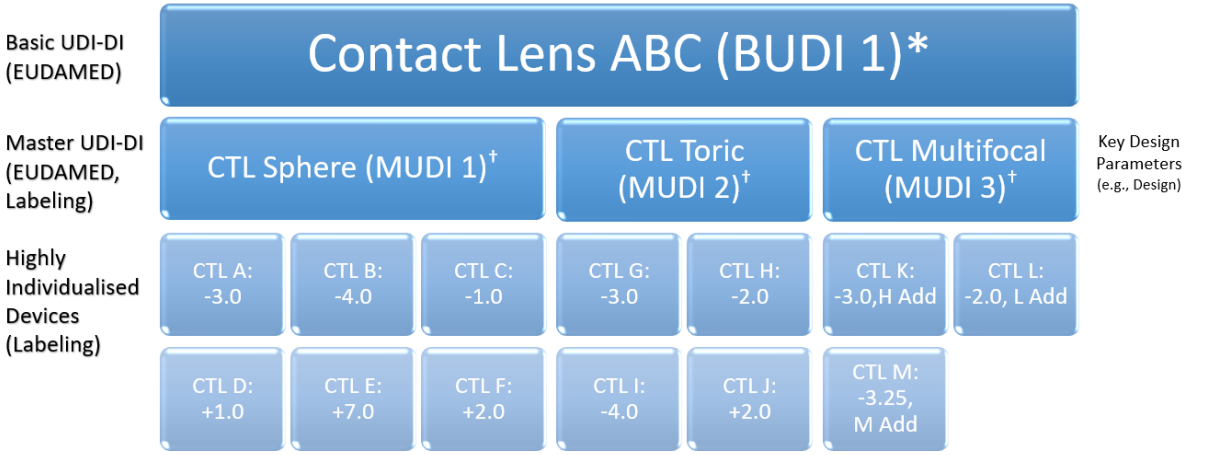

Figure 1: Representation of the hierarchy of the Master UDI-DI and Basic UDI-DI assignment

The table below compares different device identifiers and levels of identification given by the assignment of UDI-DIs to contact lenses and other devices.

Overview of the Unique Device Identifiers for contact lenses

Identifier	Other MDs	Contact Lenses (standard and MtO)	On the label	In Eudamed
Basic UDI-DI	Yes	Yes	No	Yes
Master UDI-DI / UDI-DI	UDI-DI	Master UDI-DI	Yes (either)	Yes (either)
Unit of use UDI-DI	Yes (if applicable)	No	No	N/A
Direct marking UDI-DI	Yes (if applicable)	N/A	No	N/A
UDI-PI	Yes	Yes	Yes	No[6]

[6] The UDI-PI type (whether a serial number, lot number or else is used) is indicated in the UDI/Device Registration module of Eudamed. The actual UDI-PI is reported only in the Vigilance and Post-Market Surveillance module in case of serious incidents

2.1 Master UDI-DI assignment

2.1.1 Standard contact lenses

The Master UDI-DI for standard contact lenses will be assigned to a given combination of contact lens design parameters as defined by the manufacturer, including at least the 'Base Curve' (BC) and 'Diameter', and completed with other relevant parameters as indicated on the labelling for the end-user, the eye care professional etc.

When a lens is available in one material, in spheric, toric and multifocal design variants, it would be covered by three Basic UDI-DI (one material + design type) and around 9 Master UDI-DIs, corresponding to each variant.

See some examples below:

Basic UDI-DI 1: material XY + Spheric design

- Master UDI-DI 1-1: Spheric Design **Base Curve value x, Diameter value a**
- Master UDI-DI 1-2: Spheric Design **Base Curve value y, Diameter value b**
- Master UDI-DI 1-3: Spheric Design **Base Curve value x, Diameter value b**
- Master UDI-DI 1-4: Spheric Design **Base Curve value z, Diameter value c**
- etc.

Basic UDI-DI 2: material XY + Toric design

- Master UDI-DI 2-1: Toric Design **Base Curve value x, Diameter value a**
- Master UDI-DI 2-2: Toric Design **Base Curve value y, Diameter value b**
- etc.

Basic UDI-DI 3: material XY + Multifocal design

- Master UDI-DI 3-1: Multifocal design **Base Curve value x, Diameter value a**
- Master UDI-DI 3-2: Multifocal design **Base Curve value y, Diameter value b**
- Master UDI-DI 3-3: Multifocal design **Base Curve value x, Diameter value b**
- Master UDI-DI 3-4: Multifocal design **Base Curve value z, Diameter value c**
- etc.

Note: the above examples are for explicatory purposes only.

UDI-PI

No specific production identifiers (PIs) are required to be assigned to standard contact lenses, the provisions of Annex VI Part C as regards the PIs apply.

Labelling

The rules on UDI carrier in section 4 of Part C of Annex VI to the MDR apply to the Master UDI-DI.

In figure 2 below, an example of labelling. This is for illustrative purposes only to reflect how the Master UDI-DI identifier could appear and does not reflect a requirement to align exactly as shown nor a fully compliant label. The example reflects the Automatic Identification Data Capture (AIDC) and Human Readable Interpretation (HRI) carriers, which may be combined with other information and barcoding to meet requirements set out in the MDR, in particular, when it comes to the automated identification of the individual device. Format and HRI may vary based on the designated issuing entities. The below label is based on the GS1 issuing entity[7] Master UDI-DI standard.

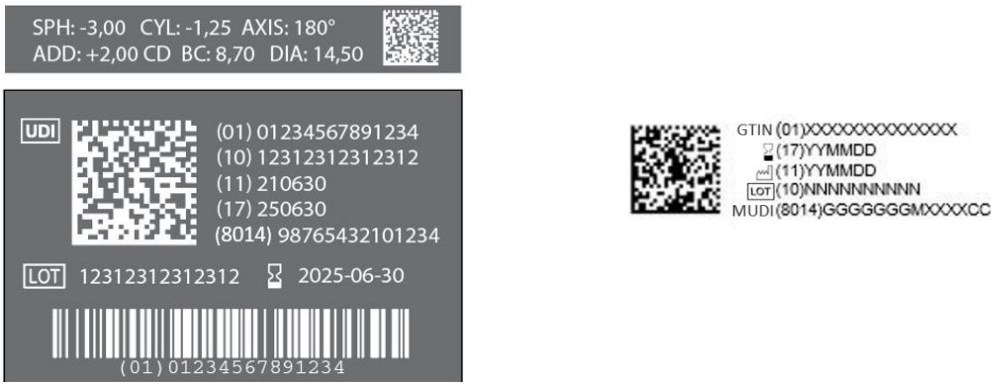

Figure 2: Example labelling for Master UDI-DI identifier

The placement of UDI carrier (including Master UDI-DI) on contact lens packaging is dependent on provisions and requirements in the MDR, specifically space constraints and sales unit requirements in Annex VI Part C 4.2 and 4.3. Requirements on labelling of contact lens blisters are dependent on space constraints and what is considered the lowest level of packaging that is used by the final user as per the MDR requirements. If contact lens blisters are considered the lowest level of packaging that is used by the final user per the MDR, the Master UDI-DI may be labelled once for a contact lens strip of e.g. 5 units, provided that the manufacturer has carried out the relevant risk management.

2.1.2 Made to order (MtO) contact lenses

The Master UDI-DI will be assigned to made to order (MtO) contact lenses based on a combination of contact lens design parameters as defined by the manufacturer and combined with other relevant parameters. The assignment of Master UDI-DI does not need to include the actual values of parameters.

Example

The contact lens design will be defined by the combination of design parameters, with the parameters including at least base curve and diameter. Examples of combination of design parameters include:

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

Spherical Design = Base Curve + Diameter + Power

Toric Design = Base Curve + Diameter + Power + Cylinder + Axis

Multifocal Design = Base Curve + Diameter + Power + Add Power

Master UDI-DI 1 = Material A, Spherical Design

Master UDI-DI 2 = Material A, Toric Design

Master UDI-DI 3 = Material A, Multifocal Design

Master UDI-DI 4 = Material B, Spherical Design

Master UDI-DI 5 = Material B, Toric Design

Master UDI-DI 6 = Material B, Multifocal Design

Note: the above examples are for explicatory purposes only.

UDI-PI

A unique lot / serial number should be used as UDI-PI for made to order contact lenses.

Labelling

The rules on UDI carrier in section 4 of Part C of Annex VI MDR apply to the Master UDI-DI.

In figures 3 and 4 below, some labelling examples for MtO contact lenses. These are for illustrative purposes only to reflect how the Master UDI-DI identifier could appear and do not reflect a requirement to align exactly as shown nor a fully compliant label. The examples reflect the AIDC and HRI carriers, which may be combined with other information and barcoding to meet requirements set out in the MDR. Format and HRI may vary based on the designated issuing entities. The labels are based on the GS1 and HIBCC issuing entities[8] Master UDI-DI standards.

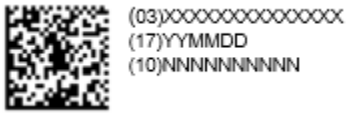

Figure 3: Example labelling for MtO contact lenses

Figure 4: Fictive example of the Master UDI-DI labelling for MtO contact lenses

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

3. Master UDI-DI assignment on container package, packaging levels and packaging variants

The Master UDI-DI may be associated to a grouping regardless of pack size that have the same combination of contact lens design parameters, which would include identification of all units of use, pack sizes and higher levels of packaging in that grouping. Pack size does not in itself impact key design parameters. Per Regulation (EU) 2017/745 Annex VI Part C, higher levels of packaging shall have their own UDI-DI. As the Master UDI-DI replaces the UDI-DI for contact lenses, higher levels of packaging shall have their own Master UDI-DI, if applicable. Quantity is a trade item level attribute, and many would fall under the same combination of contact lens design parameters.

If within the same package there are contact lenses with different Master UDI-DIs, then the package should be considered as a transport container that should not have an assigned Master UDI-UDI.

4. Vigilance reporting

4.1 Vigilance reporting for Regulation contact lenses

In case of vigilance reporting on contact lenses fully compliant with the MDR, the manufacturer should provide the full UDI (Master UDI-DI + UDI-PI) for example in the Manufacturer Incident Report (MIR) form (both when using of a PDF MIR[9] and the Eudamed Vigilance and Post-Market Surveillance module).

The provisions of Annex VI Part C MDR for the assignment of PIs apply also to contact lenses, no specific production identifiers (PIs) are required (except unique lot / serial number for MtO contact lenses). The design of the UDI carrier has to ensure the automated identification of the individual device (or the individual lot/batch of devices). Since one Master UDI-DI encompasses a range of devices, it is important that the manufacturer should provide the full UDI (Master UDI-DI + UDI-PI) it has assigned to the specific contact lense(s) involved in the incident. The UDI shall enable the retrieval of relevant data for traceability of the devices in the quality management system (QMS) of the manufacturer.

Note: due to the timeline for the application of the Master UDI-DI assignment obligation, there is a possibility that contact lenses may not yet be registered in the UDI/Devices Registration module of Eudamed when it becomes mandatory. Manufacturers should engage with an issuing entity as soon as possible, and at least before the Vigilance and Post-Market Surveillance module of Eudamed becomes mandatory[10], in order to be able to assign Master UDI-DIs in due time and to handle the reporting of vigilance cases in Eudamed.

4.2 Vigilance reporting for legacy contact lenses

The same principles as for other legacy devices apply. For information on legacy device registration in connection with vigilance reporting in Eudamed, please refer to the Q&A document for the transitional provisions and gradual roll-out of Eudamed[11], in particular Q8 and Q14.

For legacy devices that are contact lenses, the devices may be identified by Eudamed ID or UDI-DI (for instance, GTIN[12]) in combination with the UDI-PI for the purpose of vigilance reporting in Eudamed.

[9] https://ec.europa.eu/docsroom/documents/41681

[10] https://health.ec.europa.eu/medical-devices-eudamed/overview_en

[11] https://health.ec.europa.eu/medical-devices-sector/new-regulations_en#Extension

[12] https://www.gs1.org/standards/id-keys/gtin

5. Timeline for the application of the Master UDI-DI

Commission Delegated Regulation (EU) 2023/2197 on Master UDI-DI for contact lenses was published in the *Official Journal of the European Union* (OJEU) on 20 October 2023 and entered into force on 9 November 2023. It applies from 9 November 2025, so it provides for a two-year transition period as from its entry into force before the assignment of Master UDI-DI to contact lenses becomes mandatory. It also provides for the possibility for manufacturers to comply in advance, by assigning Master UDI-DIs before the mandatory application, pending the technical solution is available from the EU issuing entities.

Until the assignment of Master UDI-DI becomes mandatory, contact lenses can be placed on the market without it being assigned. However, nothing prevents the manufacturers from assigning other types of identifiers (such as GTIN or other standards) for different identification purposes or assigning a Master UDI-DI on a voluntary basis.

The obligations on UDI carriers for Master UDI-DI for contact lenses are applicable as from the date when Delegated Regulation (EU) 2023/2197 becomes applicable. The obligation to register contact lenses in Eudamed should be applicable as from when the transition period for the mandatory use of the UDI/Device Registration module expires. Legacy contact lenses can be registered in Eudamed for the purpose of serious incident reporting without a Master UDI-DI or other identifier assigned, using the equivalent Eudamed ID and Eudamed DI.

6. Device registration in Eudamed

For contact lenses, the Master UDI-DI will be registered and used in Eudamed *in lieu* of the UDI-DI when special device type 'Standard soft contact lenses' or 'Rigid gas permeable (RGP) contact lenses' or 'Made to order (MtO) soft contact lenses' or 'Made to order (MtO) rigid gas permeable contact lenses' is selected. Sizes will be registered in ranges.

Legacy contact lenses should not be registered in Eudamed unless a vigilance action is required.

More information is available in the Eudamed information centre[13] and in the user guide[14] of the UDI/Devices Registration module of Eudamed[15].

[13] https://webgate.ec.europa.eu/eudamed-help/en/welcome-to-the-eudamed-information-centre.html

[14] https://webgate.ec.europa.eu/eudamed-help/en/files/UDI%20Devices%20-%20user%20guide.pdf

[15] https://health.ec.europa.eu/medical-devices-eudamed/udidevices-registration_en