EUROMCONTACT
THE EUROPEAN ASSOCIATION OF THE
CONTACT LENS AND LENS CARE INDUSTRY

Unique Device Identifier (UDI) for contact lenses and upcoming labeling updates

Factsheet for Eye Care Professionals

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Purpose

This factsheet is designed to assist Eye Care Professionals (ECPs) to familiarize themselves with the Unique Device Identifier (UDI) system created by the Medical Devices Regulation (EU) 2017/745 (MDR) and understand its implications for contact lens labeling.

Background

The MDR, which replaced the MDD (Medical Devices Directive), establishes an **EU identification system** for medical devices based on a Unique Device Identifier (UDI). The aim of this new system is to improve the traceability of medical devices, including contact lenses. The UDI requirements apply to standard and made-to-order contact lenses but exclude custom-made lenses.

A UDI is a numeric or alphanumeric code that uniquely identifies individual devices. Manufacturers are responsible for assigning and placing UDI carriers on device labels. For contact lenses, a specific UDI system has been foreseen based on a Master UDI (MUDI). The Master UDI (MUDI) is a unique identifier assigned to a group of contact lenses that share common attributes. This identifier helps in categorizing and managing contact lenses based on their similarities, making it easier for manufacturers, regulators, and healthcare providers to track and trace these devices. **UDI-carriers will be added to contact lenses labels** using both automatic identification and data capture (AIDC) and human readable interpretation (HRI) up to **9 November 2026.**

Expected changes to contact lens labels

- **For labels with an existing AIDC:** The MUDI code will be added to the existing AIDC (e.g. 2D data matrix).
- **For labels without AIDC:** AIDC (e.g. 2D data matrix) will be added to encode all UDI information, including the MUDI.

Examples of UDI-carrier formats including a scannable 2D data matrix alongside its human-readable interpretation (HRI) :

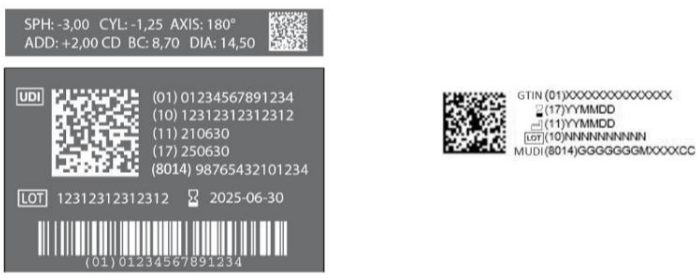

Figure 2: Example labelling for Master UDI-DI identifier

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

The examples above show the solution provided by GS1, introducing 2 new application identifiers :

- AI (8014) for standard contact lenses ;
- AI (03) for Made to Order (MtO) lenses.

What does this mean for you?

The information in the 2D barcode remains unchanged, but the new MUDI will be encoded within it.

If your processes involve scanning the AIDC on contact lens labels, ensure your systems can properly read the updated information, including the Master UDI. Consult your software provider to confirm your system's readiness or identify any required updates.

Contact lenses produced prior to 9 November 2026 are not required to have a Master UDI-DI on the label. Note, due to a combination of MDD devices, pre-MUDI MDR devices, and post MUDI MDR devices existing in the market, there will be a period of time that you may need to be able to read AIDC that both does and does not contain the MUDI code.

References :

- Regulation (EU) 2017/745 on medical devices
- Commission Delegated Regulation (EU) 2023/2197 amending MDR as regards the assignment of Unique Device Identifiers for contact lenses
- Commission Delegated Regulation (EU) 2025/788 amending Delegated Regulation (EU) 2023/2197 as regards the date of application
- MDCG 2024-14 Rev. 1 Guidance on the implementation of the Master UDI-DI solution for contact lenses
- MDCG 2025-7 Rev. 1 Position Paper: Timelines of the implementation of 'Master UDI-DI' to contact lenses and spectacle frames, spectacle lenses and ready-to-wear reading spectacles

About EuromContact

EuromContact is the European trade association for the contact lens and lens care industry. Our members are European and multinational companies as well as a network of national trade associations. EuromContact represents manufacturers of contact lenses and lens care products to EU institutions, stakeholders and the trade press.
