European Council of Optometry and Optics

EUROMCONTACT



MASTER UDI (MUDI) FOR CONTACT LENSES

What EU Optometrists and Opticians Need to Know and Do Before November 2026

Guidance for ECOO members

August 2026

01 PURPOSE OF THIS DOCUMENT

This guidance document has been prepared for ECOO members to support them in understanding and communicating the requirements of the Master Unique Device Identifier (MUDI) system for contact lenses, which becomes mandatory under EU law on 9 November 2026.

It explains what MUDI is, why it has been introduced, what will change on contact lens packaging, and what optical practices need to do (as well as what they are not required to do) in their role as distributors under the EU Medical Device Regulation (MDR) 2017/745.

02 BACKGROUND: THE EU UDI SYSTEM

The EU Medical Device Regulation 2017/745 (MDR) introduced a Unique Device Identification (UDI) system for medical devices. The purpose of the system is to provide unambiguous identification of medical devices as they move through the supply chain, supporting traceability and patient safety.

A UDI is made up of two components:

- **Device Identifier (UDI-DI):** a mandatory, fixed code that identifies the manufacturer and the specific version or model of a device. Under the GS1 standard, this is the Global Trade Item Number (GTIN).
- **Production Identifiers (UDI-PI):** variable information specific to a production run, such as the lot or batch number, expiry date and manufacturing date.

Contact lenses are Class II medical devices and are therefore subject to UDI requirements. However, because of their particular characteristics, the MDR introduces a specialised variant of the UDI for contact lenses: the Master UDI (MUDI).



03 WHAT IS THE MASTER UDI (MUDI)?

The MUDI is a unique identifier assigned not to a single product but to a group of contact lenses that share the same combination of design parameters. The minimum parameters that must match for lenses to share a MUDI are base curve and diameter, alongside the same intended purpose and risk classification.

This approach reflects the clinical reality of contact lenses: a spherical monthly lens, for example, is the same design regardless of power. Rather than assigning a unique regulatory identifier to every power variant, the MUDI identifies the design itself. Manufacturers may choose to differentiate further at their discretion, but the minimum grouping is based on base curve and diameter.

The MUDI replaces the standard UDI-DI for contact lenses in the EU regulatory system. In technical terms:

- For most markets globally, the device identifier in the barcode is the GTIN (GS1 Application Identifier 01).
- For EU contact lenses under MDR, the device identifier is a HIDRI (a Highly Individualised Device Registration Identifier) carried in GS1 Application Identifier (8014). This HIDRI is the MUDI-DI.
- For Made-to-Order (MtO) contact lenses, the GTIN encoded with Application Identifier (03) is used as the MUDI-DI instead.

The GTIN continues to appear on the label for commercial and ordering purposes. The HIDRI is the additional regulatory field introduced by the MUDI system.



04 IMPLEMENTATION DEADLINE AND TRANSITION PERIOD

4.1 The deadline

Manufacturers of contact lenses must implement the MUDI system by 9 November 2026. From this date, any contact lenses placed on the market must carry the MUDI on the label.

Contact lenses manufactured before 9 November 2026 are not required to carry the MUDI. These products may continue to be sold and dispensed without a MUDI on the label.

4.2 The transition period

Because products already in the supply chain will not carry a MUDI, there will be a period during which optical practices receive a mix of:

- Old stock (products certified under the Medical Device Directive (MDD) or placed on the market before 9 November 2026) without a MUDI on the label.
- New stock (products manufactured and placed on the market from 9 November 2026 onwards) with a MUDI on the label.

Practices and their software systems (if applicable) must be capable of processing barcodes both with and without the MUDI field during this period. This is especially important for any practice that currently scans the 2D Data Matrix barcode on contact lens cartons.

Manufacturers are encouraged to assign MUDIs voluntarily ahead of the deadline. Where a manufacturer does so, they must also label the product accordingly and register it in EUDAMED (the European Database on Medical Devices).



05 WHAT WILL CHANGE ON CONTACT LENS PACKAGING?

5.1 The barcode

For most products, the change to the label is minimal. The 2D Data Matrix (GS1 DataMatrix) barcode on the carton will be updated to include one additional data field: the MUDI (HIDRI), encoded under GS1 Application Identifier (8014). The Human Readable Interpretation (HRI) i.e. the text printed adjacent to the barcode will also show the MUDI value.

After November 2026, the 2D Data Matrix on a new contact lens carton will typically encode:

- (01) GTIN
- (17) Expiry date
- (10) Lot or batch number
- (11) Manufacturing date
- (8014) HIDRI: the MUDI-DI field

The examples below show real contact lens carton labels, illustrating exactly what the new MUDI field looks like in practice. Both labels show the same MUDI value — (8014)030065M0002276 — confirming that different power variants of the same lens design share the same MUDI.



Example carton label showing MUDI field (8014)030065M0002276 — this lens was manufactured before November 2026 and the label was updated voluntarily ahead of the deadline



A second carton of the same lens design — different power, batch and expiry, but the same MUDI value (8014)030065M0002276, demonstrating the design-level grouping

Note: These are illustrative examples from real product labelling, provided by EuroMContact. Labelling format and content may vary between manufacturers, product types, and packaging sizes.

5.2 The blister

The individual blister or unit-of-use packaging is not affected by the MUDI requirement. A UDI is only required on the blister if it is the unit of sale and is supplied without secondary (carton) packaging. In normal practice, where lenses are sold in cartons, no change is needed to the blister.

5.3 Smaller cartons

On smaller cartons (for example, single-lens packs), space constraints may mean that some currently present but non-mandatory barcodes — such as a separate GS1-128 barcode showing lot and expiry are removed. All essential UDI data will remain within the 2D Data Matrix.

5.4 Scanner compatibility (if a scanning device is used)

Most barcode scanners and practice management systems will need to be updated to correctly recognise and process GS1 Application Identifier (8014). If your practice currently scans the 2D Data Matrix barcode on contact lens cartons e.g. for stock management, patient records, or any other purpose you should contact your software provider now to confirm whether your system is compatible with the new data format and to plan any necessary updates before November 2026.



06 OBLIGATIONS FOR OPTICAL PRACTICES AS DISTRIBUTORS

Optical practices that supply contact lenses to patients are acting as distributors under the MDR and are subject to corresponding legal obligations. These obligations are relatively limited for contact lenses and it is important that members understand both what is required and what is not.

6.1 Verifying that a MUDI has been assigned (Article 14 MDR)

Before making a contact lens available to a patient, distributors must verify that the following requirements are met:

1. The device is CE marked and an EU Declaration of Conformity has been drawn up.
2. The device is accompanied by the required manufacturer information (labelling, instructions for use, etc.).
3. Where applicable, a UDI (MUDI) has been assigned by the manufacturer.

Verification may be carried out using a sampling method i.e distributors are not required to check every single box. It is recommended to establish a simple written procedure describing the sampling approach used, to demonstrate compliance in the event of an inspection by a competent authority (see template in annex). Visual verification is sufficient; there is no requirement to scan the barcode to fulfil this obligation.

In case of imported devices it is advisable to request confirmation that the importer has met the applicable obligations.

6.2 Traceability (Article 25 MDR)

Distributors must be able to identify, to the competent authority if requested:

- Any economic operator (wholesaler or supplier) from whom they directly received contact lenses.
- Any economic operator to whom they have directly supplied contact lenses.
- Any health institution or healthcare professional to whom they have directly supplied contact lenses.

Individual patients are explicitly outside the scope of Article 25 traceability obligations. Distributors are not required to maintain a record linking MUDI or UDI data to individual patients.

6.3 Storage of UDI data (Article 27 MDR)

The MDR requires economic operators to store and keep UDI data electronically only for Class III implantable devices. Contact lenses are Class II devices and there is therefore no legal obligation to store or maintain a registry of UDI or MUDI values for contact lenses.

Storing MUDI data for example, linked to stock records or lot numbers may be a useful practical tool for traceability, particularly in the event of a product recall, but it is not a regulatory requirement.

6.4 What optical practices are not required to do

To be clear, the following are not required under the MDR for contact lens distributors:

- **Scanning or recording the MUDI at individual patient level:** The MDR does not require capturing or recording the MUDI when dispensing contact lenses to individual patients.
- **Maintaining a UDI registry:** Storage of UDI data is only mandated for Class III implantable devices.
- **Scanning at a prescribed time:** The MDR does not specify a point in the process at which MUDI scanning must take place, should a practice choose to scan.

07 ACTION CHECKLIST FOR OPTICAL PRACTICES

The following checklist summarises the steps optical practices should take before November 2026.

☐	Contact your practice management software provider (if applicable) as soon as possible to confirm whether your system will correctly handle the new MUDI data field (GS1 Application Identifier 8014).
☐	Confirm whether your barcode scanner hardware (if one is used) requires a firmware or configuration update to read the new GS1 AI (8014) field.
☐	Establish a written sampling procedure for verifying MUDI/UDI assignment on incoming contact lens stock, to demonstrate compliance if inspected (see template in Annex).
☐	Brief your team on the label changes: new contact lens cartons will display an additional code, the MUDI, in the 2D Data Matrix barcode and its adjacent human-readable text.
☐	Update stock management processes where necessary to handle the transition period, during which you will receive a mix of stock with and without the MUDI on the label.
☐	Review your distributor traceability records to ensure you can identify your contact lens suppliers and the health professionals to whom you directly supply.
☐	No change is required to patient dispensing records: there is no legal obligation to record the MUDI at individual patient level.

Disclaimer: This guidance has been prepared by ECOO for its members. It is intended for general information purposes and does not constitute legal advice. Practices should consult their national competent authority or seek legal counsel for jurisdiction-specific compliance questions.

ANNEX
UDI/MUDI SAMPLING PROCEDURE

Verification of UDI/MUDI assignment on incoming contact lens stock

Practice name	
Responsible person	
Date adopted	

Purpose

This document records how this practice verifies that a UDI (and from 9 November 2026, a Master UDI) has been assigned to incoming contact lens stock, as required under Article 14(2)(d) of EU MDR 2017/745. It is kept on file as evidence of compliance in the event of inspection.

What is checked

For each sampled delivery, we confirm that:

☐	The CE mark is visible on the carton.
☐	A 2D Data Matrix barcode is present on the carton.
☐	From 9 November 2026 onwards: the Human Readable Interpretation (HRI) text next to the barcode includes a value starting with (8014) — this is the MUDI. Stock manufactured before that date is exempt and should be noted as such.

Sampling method

We do not check every unit. Under MDR Article 14(2), a representative sample is sufficient. Our approach:

- Routine delivery from an established supplier: (DEFINE e.g. check at least 1 unit per product line)
- First delivery from a new supplier: (DEFINE e.g. check at least 3 different product lines)
- After a failed check: check 100% of units from that supplier

Units are selected from different positions in the delivery and across different lens types where possible. Visual inspection is sufficient; scanning is not required for compliance purposes.

If a check fails

- Do not make the affected stock available to patients.
- Contact the supplier to raise the issue.
- Record the non-conformance in the log below.
- If unresolved and the device appears to present a serious risk, inform the competent authority.

Records

Each check is logged below. Records are retained for a minimum of [insert period — typically 10 years for Class II devices] and made available to the competent authority on request.

Approved by (name)			
Signature		**Date**	

Verification Log

Complete one row per delivery check. Add additional sheets as needed.

Date	Supplier	Products checked	Units sampled	UDI / MUDI present?	CE mark present?	Pass / Fail	Checked by

Template prepared for ECOO members and needs to adapt to practice's circumstances.
This template and guidance document does not constitute legal advice.