



TRACEABILITY OF MEDICAL DEVICES

UDI, Master UDI-DI, EUDAMED: understanding the new European requirements and their implications for professionals.

Medical device traceability is evolving in Europe. With the deployment of the EUDAMED database and the introduction of new product identification rules, manufacturers and distributors in the optical and hearing care sectors are directly concerned.

Some requirements already apply, while new deadlines are approaching: 9 November 2026 for contact lenses and 1 November 2028 for spectacle frames, ophthalmic lenses and ready-to-wear reading spectacles.

Which identifiers are involved? What are they used for? How do they relate to commercial product references and production information?

Normeyes provides an overview.

1. Why strengthen medical device traceability?

Regulation (EU) 2017/745 on medical devices (MDR) provides for a harmonised system of unique device identification, known as UDI (Unique Device Identification), or IUD in French.

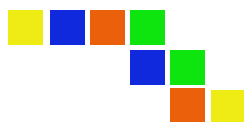
This system aims to:

- Facilitate the identification of medical devices throughout their life cycle
- Improve market surveillance and the management of product recalls
- Enhance patient and user safety
- Ensure greater transparency of information on devices marketed in Europe

This system applies to medical devices covered by the European Regulation, across all medical specialties, subject to the rules and exceptions provided for in the legislation.

The optical and hearing care sectors are therefore also concerned. For certain optical products offering numerous possible configurations, specific provisions have been introduced through the Master UDI-DI to adapt their identification to the particular characteristics of these devices.

Implementing this system involves assigning regulatory identifiers, displaying them on product labels and registering the required data in EUDAMED.



2. UDI, Basic UDI-DI, Master UDI-DI: understanding the differences

Several identifiers are used within the European system. Each serves a specific purpose.

2.1 The Basic UDI-DI: identifying a family of devices

The Basic UDI-DI groups together devices that share, in particular, the same intended purpose and common essential characteristics.

It serves as a regulatory reference used in technical documentation, declarations of conformity and the EUDAMED database.

It does not appear on the product label.

Under the GS1 system, this identifier is based on a Global Model Number (GMN), composed of the manufacturer's company prefix, a reference and check characters.

2.2 The UDI: identifying the device and its production information

The UDI consists of two complementary components:

- **UDI-DI (Device Identifier)** : the device identifier, used to identify a device model or version.
- **UDI-PI (Production Identifier)** : applicable production information, such as the lot number, serial number, manufacturing date or expiry date.

The UDI appears on the label in accordance with the applicable rules, in both human-readable and machine-readable forms (including barcodes or two-dimensional codes). The format used depends on the coding system chosen by the manufacturer.

2.3 The Master UDI-DI: grouping highly individualised devices

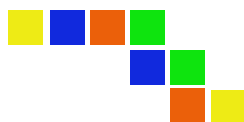
Certain optical products offer a particularly large number of possible combinations: prescriptions, dimensions, design characteristics, etc.

Assigning a separate UDI-DI to each of these combinations would considerably increase the number of identifiers and regulatory registrations.

To address this issue, the European Union introduced the **Master UDI-DI**.

It allows devices sharing a defined combination of design characteristics to be grouped under a single identifier.

It serves as the UDI-DI for the products concerned and remains associated with the applicable production information (UDI-PI).



→ An example for spectacle frames

For a given manufacturer, spectacle frames with the same construction and material may belong to the same regulatory device family, identified by a Basic UDI-DI.

Within this family, the frame size (lens horizontal boxed dimension) is taken into account when assigning the Master UDI-DI.

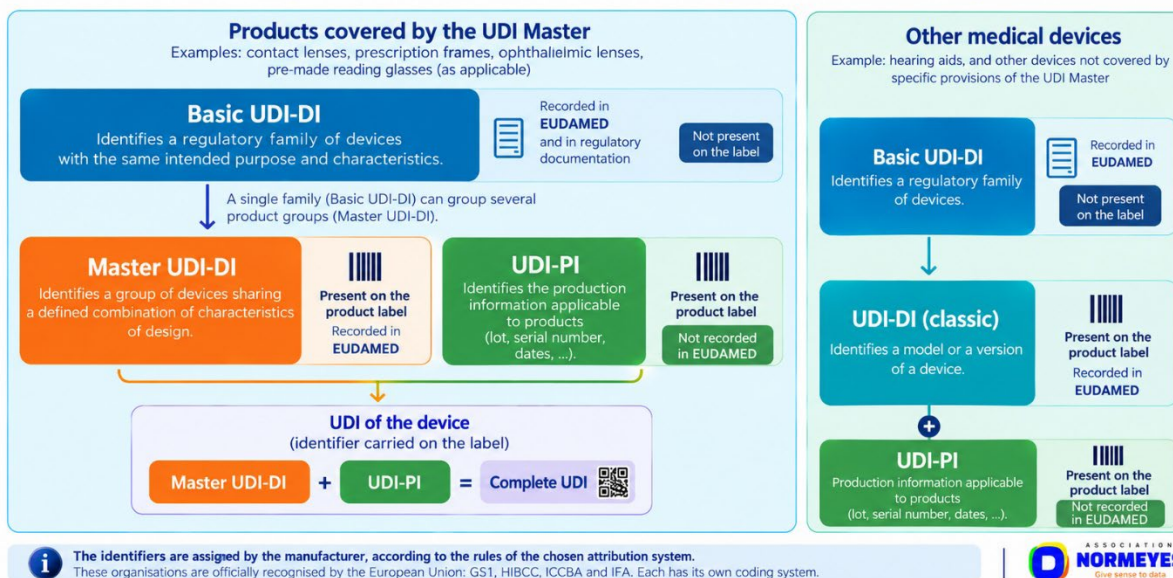
Several commercial models with the same construction, material and frame size may therefore share a Master UDI-DI, whereas a change in frame size requires the assignment of a new Master UDI-DI.

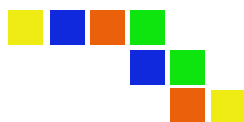
The principle is similar for ophthalmic lenses and ready-to-wear reading spectacles, with grouping criteria adapted to their characteristics.

👉 **Key point:** a Master UDI-DI does not necessarily correspond to a single commercial product reference. Several products may share the same regulatory identifier while retaining their own catalogue references.

UDI identifiers: how do they fit together?

Each identifier has a specific function and is not necessarily found in the same place.





3. How are the identifiers constructed?

Assigning regulatory identifiers is the responsibility of the legal manufacturer, in accordance with European rules and those of the chosen issuing entity.

Four issuing entities are officially recognised by the European Commission: GS1, HIBCC, ICCBBA and IFA. Each has its own coding system.

⚠ Please note: the examples below are based on the GS1 standard, widely used in commercial and logistics exchanges. Other identification systems may therefore be used, in accordance with the rules of the recognised issuing entities.

3.1 Made-to-Stock products

These are products generally manufactured before an order is placed and which may be held in stock by the manufacturer, distributor or professional.

Examples include spectacle frames, ready-to-wear reading spectacles and stock lenses.

When these products already have a GTIN, a commercial identifier used for trading and logistics, the Master UDI-DI is constructed using a specific identifier called **HIDRI (Highly Individualised Device Registration Identifier)**.

👉 **The HIDRI identifies the regulatory group**, while the GTIN continues to identify the commercial product reference.

3.2 Made-to-Order products

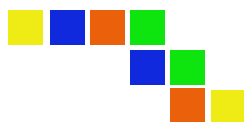
Certain devices are manufactured or configured based on a prescription, without having a pre-existing GTIN for a stock product.

This is particularly the case for certain ophthalmic lenses surfaced to order.

In this situation, the GS1 standard provides for a specific identifier called **MtO GTIN (Made-to-Order GTIN)**, which can serve as the Master UDI-DI.

In both cases, the applicable production information complements the regulatory identifier.

👉 **This distinction makes it possible to retain the references needed for commercial exchanges while meeting the regulatory requirements for grouping devices.**



4. What are the main regulatory deadlines?

The UDI system and EUDAMED are being implemented progressively. Registration obligations in EUDAMED and those relating to the Master UDI-DI follow separate timelines.



■ 28 May 2026 – EUDAMED

Use of the first four modules of the European EUDAMED database became mandatory: registration of economic operators, registration of devices and UDIs, notified bodies and certificates, and market surveillance.

→ Transitional provisions

Additional deadlines are nevertheless provided for certain registrations, particularly those concerning devices already marketed:

- **28 November 2026:** deadline for registering certain devices already placed on the market before 28 May 2026 and which continue to be placed on the market.
- **28 May 2027:** deadline for registering certain certificates issued under the European MDR/IVDR regulations before 28 May 2026.

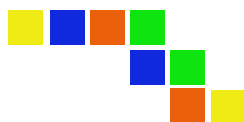
These deadlines should not be confused with the specific application dates for the Master UDI-DI.

■ 9 November 2026 – Contact lenses

The new Master UDI-DI assignment rules become applicable to contact lenses, in accordance with Commission Delegated Regulation (EU) 2023/2197, as amended by Commission Delegated Regulation (EU) 2025/788.

■ 1 November 2028 – Spectacle frames, lenses and ready-to-wear reading spectacles

The Master UDI-DI becomes applicable to prescription spectacle frames, ophthalmic lenses and ready-to-wear reading spectacles, in accordance with Commission Delegated Regulation (EU) 2025/1920.



→ Do products already manufactured need to be relabelled?

The new requirements relating to the Master UDI-DI do not require retroactive relabelling of products manufactured before their respective application dates, without prejudice to other applicable regulatory requirements.

What about hearing aids?

Hearing aids are also covered by the European Medical Device Regulation.

They are subject to the standard UDI system and the corresponding identification and registration requirements in EUDAMED.

However, the specific Master UDI-DI provisions applicable to highly individualised optical products do not apply to hearing aids.

5. What are the implications for industry professionals?

Beyond the regulatory assignment of identifiers, their implementation raises several practical questions.

For manufacturers, this includes defining product groupings, assigning identifiers, adapting labels and information systems, and completing the necessary regulatory registrations.

For distributors, opticians and hearing care professionals, the obligations involve checking certain regulatory information and verifying the compliance of the devices they distribute.

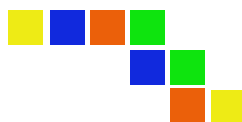
Device identification, label scanning and access to traceability information also represent operational challenges for the entire industry.

6. Normeyes and product traceability

Identification and traceability issues are closely linked to the work initiated by Normeyes on the exchange of product data.

An initial discussion group bringing together various industry stakeholders was held on 13 October 2026.

These discussions are part of Normeyes' mission: to facilitate and harmonise data exchanges between professionals in the optical and hearing care sectors.



FURTHER INFORMATION

GS1 France — Webinar held on 1 October 2026

A presentation on the regulatory identification of medical devices and the implementation of the Master UDI-DI in the optical industry, including practical feedback and experience.

[Watch the GS1 webinar replay](#)

GS1 France — Information on the Master UDI-DI

A resource providing further information on the new European requirements, GS1 identifiers and their application to optical products.

[Consult the GS1 France documentation](#)

European regulations and guidance documents

- [Regulation \(EU\) 2017/745 on medical devices](#)
- [Commission Delegated Regulation \(EU\) 2025/788 — Contact lenses](#)
- [Commission Delegated Regulation \(EU\) 2025/1920 — Spectacle frames, lenses and ready-to-wear reading spectacles](#)
- [MDCG 2024-14 Rév. 1](#) and [MDCG 2025-8 Rév. 1](#) guidance documents on the implementation of the Master UDI-DI.
- [European Commission — EUDAMED](#)