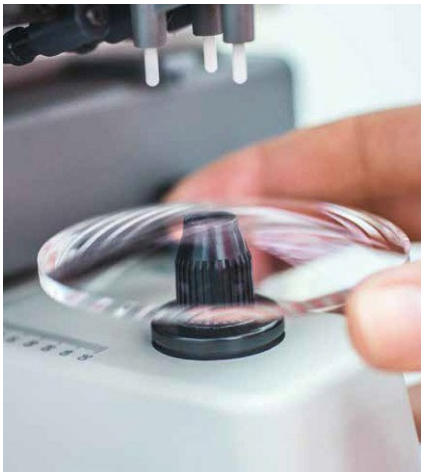
The Global Language of Business

Global Standards Management Process

New EU requirements for medical devices identification (i.e. “Master UDI-DI”)

Mission-specific working group

Call to Action



The European (EU) Commission submitted a work request to develop the creation of “Master UDI-DI" for spectacle frames, spectacle lenses and ready-to-wear reading spectacles as part of the UDI requirements based on the European Medical Device Regulation (MDR).

What business challenges are being addressed?

The purpose of the Master UDI-DI is to group devices with a high-level of individualization, spectacle frames, spectacle lenses and ready-to-wear reading spectacles, to reduce the volume of data entries in the UDI module of EUDAMED (i.e. the EU UDI database). Also, additional Application Identifiers for clinical specifications will need to be discussed and developed to provide more granular information about the products

Background

Article 27 of the MDR states that the manufacturer should assign a UDI to devices before placing them on the EU market and to provide the data elements referred to in Annex VI part B and C to the UDI module in EUDAMED.

However, for certain devices with a high level of individualisation, there is a risk of disproportionate UDI-DI (i.e. GTIN) data entries in the EUDAMED database, with limited value for regulatory purposes and a risk of substantially compromising database performance.

To enable manufacturers to fulfil their obligations regarding UDI and avoid disproportionate data entries in EUDAMED which may also affect operability of the system, a specific UDI assignment solution for highly individualised products (previously including contact lenses and now focusing on spectacle lenses, spectacle frames and ready-to-wear spectacles) should be developed, to allow grouped reporting of UDI-DI (i.e. GTIN) to EUDAMED.

The GSMP is a community- based forum for businesses facing similar problems to work together and develop standards-based solutions to address them. Active GSMP participants represent industries ranging from retail and consumer goods to fresh foods, healthcare, transport and logistics, government and more—a healthy mix of business and technical people from nearly 60 countries.

Impact

This is a request from the EU Commission to all four Issuing Entities and not being able to provide the required standards would put the GS1 status as an Issuing Entity at high risk and prevent affected medical device manufacturers who then cannot use GS1 to fulfil the EU legal requirements.

Working group objectives

The working group will develop the appropriate solution for the new level of identification required by European Medical Device Regulation.

Who should join this working group?

In addition to the experts from the medical devices industry and solution providers active in the sector, GS1 is specifically looking for participation of eyewear and medical device manufacturers of other highly individualised products. Should the need arise, the Commission will propose new delegated acts to further extend the Master UDI-DI concept to other devices, but for the moment, spectacle frames, spectacle lenses and ready-to-wear reading spectacles are the only products in scope for this Mission Specific Work Group.

Suggested but not required skillsets, both business and technical (public policy and regulatory affairs, expertise in traceability systems, etc.):

- Solid understanding of the GS1 system of standards
- Knowledge of regulatory affairs, particularly EU related and public policy
- Familiarity with medical device design, registration and manufacturing practices
- Involvement in the distribution and administration of medical devices
- Understanding of the global healthcare direction of identification

How will this working group operate?

This working group will follow the GS1 Global Standards Management Process:

Define business requirements—collect input from the industry, MOs and hospital communities.

Refine and develop rules—experts draft relevant standards and present it to industry, MOs and hospitals for approval.

Develop and Approve—standards are approved by the standards development community, ratified by GS1 governance bodies and published.

Next Steps

1. **Sign up for the Working Group** and join the Kick-Off meeting on 15 May 2025 at 15:30 CET / 9:30 EDT Register now and find more details here
2. **Contribute to the process:** Bring your expertise and insights to ensure the updated rules reflect the needs of the healthcare community.
3. **Help or questions?**
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Collaborate with us to advance healthcare product identification. Together, we can ensure safer, more efficient, and globally harmonised healthcare supply chains.

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