WR #	GSCN Name	Effective Date
WR25-00035	AIDC Application Standard Master UDI-DI for registration of certain type of devices with EUDAMED	Jun-2026

Associated Work Request (WR) Number:

N/A

Background:

The European (EU) Commission requires the development of a "MUDI-DI" for implementation of a new level of eyewear product identification for "highly individualised devices" as part of the UDI requirements based on the European Union Medical Device Regulation (MDR). EU COM will require compliance with the Unique Device Identification (UDI) system for medical devices (**Regulation (EU) 2017/745**) The resulting solution to support these regulations will be focused solely on the Healthcare Industry and will not apply to other industries unless a future use case is identified. The resulting solution to support these regulations will be focused on supporting the EU.

GS1 is one of the UDI issuing entities designated by the European Commission and must continue to meet this UDI issuing entity selection criteria. As a result, GS1, like the other UDI issuing entities, has been tasked by the European Commission to provide a solution to implement the "MUDI-DI". GS1 is the most used identification system for UDI implementation and as such, our users expect GS1 to offer an appropriate identifier to implement the "MUDI-DI". Internal analysis of the GS1 standards for identification by GS1 Global Office has concluded that today GS1 does not already have an appropriate identifier to meet the business needs expressed for the "MUDI-DI". *The EU Commission published the Commission Delegated Regulation (EU) 2025/1920 of 12 June 2025 amending Regulation (EU) 2017/745 of the European Parliament and of the Council, as regards the assignment of Unique Device Identifiers for spectacle frames, spectacle lenses and ready-to-wear reading spectacles the 23rd of September 2025 to the OJEU*

As a Designated EU issuing entity for UDI, GS1 must develop specifications and rules for the "MUDI-DI" 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 has been developed to allow grouped reporting of highly individualised device data to EUDAMED.

Disclaimer

Optional

Not applicable

Rules

Not applicable

Data carrier specification

Carrier choices

The data carriers required to carry a DigSig are listed below however specifications for data carriers are established with the application standards for the GS1 Identification keys. In some applications, one of the data carriers below are permitted without needing any other data carriers on the entity being identified. In other application standards, one of the data carriers below are permitted in addition to another data carrier that is incapable of encoding DigSig (e.g., EAN/UPC, GS1-128, ITF-14, GS1 DataBar)

- GS1 DataMatrix
- GS1 QR Code
- Data Matrix (GS1 Digital Link URI)
- QR Code (GS1 Digital Link URI)
- EPC/RFID (see section 3.11 and the most recent version of the GS1 EPC Tag Data Standard (TDS))

Symbol X-dimension, minimum symbol height and minimum symbol quality

To determine which symbol specification table is applicable, please refer to the relevant application standard for the required GS1 key, in section 2.

Symbol placement

Not applicable

Unique application processing requirements

For a description of processing requirements, see section 7.

2.6.17 Restricted application – highly individualised device identifier via Master Unique Device Identifier – Device Identifier (MUDI-DI)

Application description

MUDI-DI meets a EUDAMED registration requirement for highly individualised medical devices. The first published regulatory requirement covereds contact lenses, per both Made-to-Stock (standard contact lenses per regulation (EU) 2017/745 as amended 7 October 2023) and Made-to-Order contact lenses. The EU Commission published the additional Commission Delegated Regulation (EU) 2025/1920 of 12 June 2025 amending Regulation (EU) 2017/745 of the European Parliament and of the Council, as regards the assignment of Unique Device Identifiers for spectacle frames, spectacle lenses and ready-to-wear reading spectacles the 23rd of September 2025 to the OJEU.

This restricted application now covers contact lenses, spectacle frames, spectacle lenses and ready-to-wear reading spectacles only and fFuture regulation(s) may cover additional device types.

MUDI-DI permits consolidated EUDAMED registration of standard contact lenses, spectacle frames, spectacle lenses and ready-to-wear reading spectacles with similar clinical parameters sharing the same combination of design parameters according to identifiers specified per the two scenarios below:

- For devices that are currently identified by GTIN, MUDI-DI, not GTIN, serves as the UDI-DI in markets utilising MUDI-DI requirements, for markets not utilising MUDI-DI requirements, the GTIN serves as the UDI-DI requirement. For MUDI-DI the Highly Individualised Device Registration Identifier (HIDRI): AI (8014) is used instead of GTIN for device registration within

EUDAMED. The Highly Individualised Device Registration Identifier (HIDRI) is a restricted application use of the GS1 Global Model Number (GMN). GTINs allocated according to existing rules associated with AI (01) for Made-to-Stock trade items, will continue to be used for these devices to support current business processes. Therefore, AI (01) and related UDI-DI production identifiers (e.g., lot number, serial number, production date) would appear with AI (8014) on product labelling for Made-to-Stock contact lenses, spectacle frames, spectacle lenses and ready-to-wear reading spectacles in the EU.

- For Made-to-Order devices where GTIN is not currently used, a Made-to-Order GTIN SHALL be used in conjunction with a compound GS1 identifier via ~~key component (e.g.,~~ IDI production identifier lot number or~~,~~ serial number~~)~~. This GTIN SHALL be used as the MUDI-DI and therefore the UDI-DI. This GTIN SHALL be qualified using AI (03) not AI (01) to signal scanning/reading systems that the compound ~~GTIN key~~ GS1 identifier is required and that the GTIN itself is allocated according to Made-to-Order GTIN rules rather than the current Made-to-Stock rules. This GTIN may be a GTIN-12, GTIN-13 or a GTIN-14, but when it is registered in EUDAMED, it is stored in a 14-digit format.

The MUDI-DI, whether the Highly Individualised Device Registration Identifier (HIDRI) or Made-to-Order GTIN, once assigned, SHALL NOT be reissued.

The MUDI-DI SHALL be used for EUDAMED Registration of standard contact lenses, spectacle frames, spectacle lenses and ready-to-wear reading spectacles and the following applies:

~~The MUDI-DI SHALL only be used for standard contact lenses that will be registered in EUDAMED per European regulations and the following applies:~~

GS1 key

Required

For devices currently utilising GTIN per existing (Made-to-Stock) GS1 Healthcare GTIN Allocation Rules Standard

- Highly Individualised Device Registration Identifier (HIDRI) SHALL be used as the MUDI-DI (UDI-DI).
- GTIN (SHALL be used for current business processes)

For Made-to-Order devices not currently identified by a GTIN:

- Made-to-Order GTIN SHALL be used as the MUDI-DI (UDI-DI)
- Made-to-Order GTIN in conjunction with a compound GS1 identifier ~~key data element~~ (e.g., lot number, serial number) SHALL be used for current business processes where GTIN alone is insufficient to uniquely identify the device)

Rules

See section 4.13

For devices using current GS1 Healthcare GTIN Allocation Rules Standard used for Made-to-Stock products, GTIN SHALL continue to be used for current business processes and the Highly Individualised Device Registration Identifier (HIDRI) SHALL be used as the MUDI-DI (UDI-DI) according to the following rules:

- The Highly Individualised Device Registration Identifier (HIDRI) SHALL be used as MUDI-DI and SHALL NOT be used to identify the device for the purpose of trade where Global Trade Item Number (GTIN) is used today.
- The GTIN SHALL NOT be used for MUDI-DI registration purposes in EUDAMED where the Highly Individualised Device Registration Identifier (HIDRI) serves as the MUDI-DI (UDI-DI).
- At any given time, the relationship between the Highly Individualised Device Registration Identifier (HIDRI) / (MUDI-DI) and a Made-to-Stock GTIN using AI (01) is 1:n (can be one to one or one to many), meaning the Highly Individualised Device Registration Identifier (HIDRI) / (MUDI-DI) can be related to more than one Made-to-Stock GTIN.
- As the Highly Individualised Device Registration Identifier (HIDRI) is stored within the UDI-DI field within EUDAMED, this element string SHALL contain at least one non-numeric character

within the "grouping reference" data structure to ensure against any potential conflict with existing GTINs.
- In documentation, the MUDI-DI shall be displayed per GMN rules found in section 2.6.13.
- Allocation of the Highly Individualised Device Registration Identifier (HIDRI) to register a family of Made-to-Stock contact lenses, spectacle frames, spectacle lenses or ready-to-wear reading spectacles as the MUDI-DI is made per the discretion of the brand owner, but in compliance with EU regulatory requirements based on the EU Medical Device Regulation (MDR), relevant delegated regulations and guidance documents.

For Made-to-Order devices not currently identified by a Made-to-Stock GTIN, a Made-to-Order GTIN SHALL be used as the MUDI-DI (UDI-DI) for EUDAMED registration according to the following rules:

- The Made-to-Order GTIN SHALL be used as a Global Trade Item Number (GTIN) in conjunction with a compound ~~GTIN key component~~GS1 identifier (e.g., lot number, serial number) in order to create a unique trade item identifier.
- The Made-to-Order GTIN SHALL be used for EUDAMED registration purposes as the MUDI-DI (UDI-DI).
- In documentation, the MUDI-DI shall be displayed as a single data field, but formatting such as bold or italics may be used within text representation of the identifier to increase efficiency and accuracy of key-entry.
- Allocation of the Made-to-Order GTIN for a family of Made-to-Order contact lenses, spectacle frames, spectacle lenses or ready-to-wear reading spectacles ~~-~~is made per the discretion of the brand owner, but in compliance with EU regulatory requirements based on the EU Medical Device Regulation (MDR), relevant delegated regulations and guidance documents.
- The same GTIN value SHALL NOT be used with AI (01) and AI (03).

Attributes

Required

Where one Made-to-Order GTIN with AI (03) can support requirements related to specific use by a patient or the purpose of trade, intended use, or point-of-care and EUDAMED registration of highly individualised devices sharing the same combination of design parameters ~~similar characteristics~~, in the context of the EU UDI requirements for contact lenses, spectacle frames, spectacle lenses or ready-to-wear reading spectacles there SHALL BE:

a. no requirement to conform to the existing GS1 Healthcare GTIN Allocation Rules Standard and

b. Made-to-Order GTIN SHALL be used in conjunction with a compound GS1 identifier via UDI production identifier lot number or serial number.~~no mandatory requirement for lot number or serial number (beyond that specified by regulation) to ensure unique identification because there is a one-to-one GTIN to device relationship.~~

~~For contact lenses registered using MUDI-DI in EUDAMED, where MUDI-DI is a MtO GTIN, and where the contact lenses must be distinguishable from other contact lenses consolidated by the same MtO GTIN (MUDI-DI) for specific use by a patient or the purpose of trade, intended use, or point-of-care, each contact lens SHALL be uniquely identified and marked. Where one GTIN with AI (03) is used to support EUDAMED registration of highly individualised devices sharing similar characteristics and the GTIN cannot support distinguishing one device from another, there SHALL BE~~When MUDI-DI uses a MtO GTIN for contact lenses, spectacle frames, spectacle lenses, or ready-to-wear reading spectacles registered using MUDI-DI in EUDAMED, trade items must be distinguishable from each other when consolidated by the same MtO GTIN (MUDI-DI) for specific use by a patient or for the purpose of trade, intended use, or point-of-care. Each contact lens, spectacle frames, spectacle lenses or ready-to-wear reading spectacles SHALL be uniquely identified and marked where one GTIN with AI (03) is used to support EUDAMED registration of highly individualised devices sharing same combination of design parameters and where the GTIN cannot support distinguishing one device from another, there SHALL BE:

a. no requirement to conform to existing GS1 Healthcare GTIN Allocation Rules Standard and:

b. GTIN with another compound ~~key data~~GS1 identifier ~~element~~ that ensures unique identification (e.g., lot number, serial number) SHALL be used to ensure unique identification, for these extra regulatory requirements, because there is a one-to-many GTIN

to device relationship.
Optional

See section 3.2 - GS1 Application Identifiers in numerical order for a complete list of all GS1 Application Identifiers.

Data carrier specification

Carrier choices

- See the "data carrier specification carrier choices" recommendations on preferred options, options in addition to the barcode and other acceptable options found at the end of Section 2.1.5 Healthcare primary packaging (non-retail trade items) which apply to Section 2.1.6 Healthcare secondary packaging (regulated healthcare retail consumer trade items) as well.

Note: If the item is also scanned as a retail trade item a barcode that conforms to retail specifications is also required.

Symbol X-dimensions, minimum symbol height and minimum symbol quality

Highly individualised medical devices will require MUDI-DI but the symbol specifications for the device itself SHALL NOT change. These specifications are found in the relevant application standard for the device as determined by the brand owner of the device. For a list of applications and their associated symbol specification tables, see section 2.7.

Excerpts of Table 2-37 below provide relevant application standards.

Application	See section	SST(s)
Healthcare primary packaging (non-retail trade items)	2.1.5	6
Healthcare secondary packaging (regulated healthcare retail consumer trade items)	2.1.6	8 or 10

Symbol placement

All the symbol placement guidelines defined in section 6.

Unique application processing requirements

For a description of processing requirements, see section 7.

2.7 Summary of applications and operative scanning environments

Table 2-37 provides a cross-reference for all system applications defined in section 2 and the GS1 symbol specification tables (SSTs) in section 5. The application where the barcode will be used needs to be determined prior to locating the correct symbol specification table (SST) entry. Use the "SST(s)" column to find the SST appropriate for the application area. Because most application areas provide a reference to two symbol specification tables based on the operative scanning environment, a decision must be made between the two. See the decision tree in Figure 5-68 to determine the correct symbol specification table.

Table 2-37 Areas of GS1 system application

Application	See section	SST(s)
Fixed measure trade items scanned at retail POS using:	2.1.3	
GTIN-12 or GTIN-13	2.1.3.1	1
GTIN-12 carried by a UPC-E barcode	2.1.3.2	1
GTIN-8	2.1.3.3	1
Hardcover books and paperbacks scanned at retail POS using ISBN, GTIN-13, or GTIN-12	2.1.3.4	1

- Software versions for regulated healthcare device software.
- Commercially available office productivity software (Microsoft® Word 2013 version 15.0.4701.1001, Adobe® Reader® XI version 11.0.10).

This AI may be combined with AI 10 (lot/batch) when the manufacturer decides that both lot and version control are required to meet regulatory or commercial requirements.

The data is alphanumeric and may include all characters contained in Table 7-20~~Table 7-20~~.

GS1 Application Identifier	Software version
8 0 1 2	X_1 ——variable length——› X_{20}

The data transmitted by the barcode reader means that the element string denoting a software version has been captured. As this element string is an attribute of a software trade item, it must be processed with the GTIN of the software to which it is related (see section 4.13 *Data relationships*). When indicating this element string in the non-HRI text section of a label, the following data title SHOULD be used: **VERSION**

3.9.13 Global Model Number (GMN): AI (8013)

The GS1 Application Identifier (8013) indicates that the GS1 Application Identifier data field contains a GMN (Global Model Number). The GMN is used for the unique identification of a product model.

Note: This element string SHALL NOT be used to identify the entity as a trade item.

The GS1 Company Prefix (see section 1.2.3.3) is allocated by GS1 Member Organisations to the brand owner that allocates the GMN. It makes the number unique worldwide.

The structure and content of the model reference is at the discretion of the brand owner. It may contain all characters listed in Table 7-20~~Table 7-20~~.

The check character pair is explained in section 7.9.5. Its verification, which must be carried out in the application software, ensures that the identifier is correctly composed.

The total length of the GMN including the check characters SHALL NOT exceed 25 characters.

GS1 Application Identifier	Global Model Number (GMN)							
	GS1 Company Prefix ——›			Model reference ——›			Check characters	
8 0 1 3	N_1 ...	N_i	X_{i+1} ...	variable length		$X_{j\ (j<=23)}$	X_{j+1}	X_{j+2}

When indicating this element string in the non-HRI text section, the following data title SHOULD be used: **GMN**

Regulated healthcare medical devices

For regulated healthcare medical devices, the GMN SHALL NOT be used in any labelling, physical marking, or GS1 AIDC data carrier on associated trade items.

When indicating the Basic UDI-DI (GMN) on documents or certificates, the following data title SHOULD be used: **GMN**

The Application Identifier (AI) 8013 SHALL be excluded in such documents and certificates.

For medical devices that fall under the EU regulations (see section 2.6.13).

3.9.14 Highly Individualised Device Registration Identifier (HIDRI): AI (8014)

The GS1 Application Identifier (8014) indicates that the GS1 Application Identifier data field contains the Highly Individualised Device Registration Identifier (HIDRI) but are currently identified with a made-to-stock GTIN for other business purposes. It is used for the unique identification of a family of standard contact lenses, spectacle frames, spectacle lenses and ready-to-wear reading spectacles that will be registered in EUDAMED (European database on medical devices).

The structure and content of the grouping reference are at the discretion of the brand owner. It may contain all characters listed in Table 7-20~~Table 7-20~~.

The check character pair is explained in section 7.9.5. Its verification, which must be carried out in the application software, ensures that the identifier is correctly composed.

As the Highly Individualised Device Registration Identifier (HIDRI) is stored within the UDI-DI field within EUDAMED, this element string SHALL contain at least one non-numeric character within the “grouping reference” data structure to ensure against any potential conflict with existing GTINs.

GS1 Application Identifier	Highly Individualised Device Registration Identifier (HIDRI)		
	GS1 Company Prefix →	Grouping reference →	Check characters
8 0 1 4	N_1 … N_i	X_{i+1} … variable length $X_{j\ (j<=23)}$	X_{j+1} X_{j+2}

When indicating this element string in the non-HRI text section, the following data title SHOULD be used: **MUDI**

Note: This element string SHALL never be used to identify the entity as a trade item. The GS1 Company Prefix (see section 1.2.3.3) is allocated by GS1 Member Organisations to the brand owner that allocates the MUDI-DI. It makes the number unique worldwide. The MUDI-DI can be used in any labelling, physical marking, or GS1 AIDC data carrier on associated trade items. For the purpose of EUDAMED access, HIDRI is sufficient as a standalone key. When used in a barcode with production identifiers (e.g., lot number, serial number), HIDRI shall be associated with GTIN as the Application Identifiers for production identifiers have a mandatory association with GTIN

Note: This element string can be up to 25 characters in length and can go as low as 8 to 15 characters and shall include the GS1 Company Prefix, at least one non-numeric character as the grouping reference, and the check character pair.

3.9.15 Global Service Relation Number (GSRN): AIs (8017, 8018)

The GS1 Application Identifiers (8017, 8018) indicate that the GS1 Application Identifier data field contains a GSRN (Global Service Relation Number). The GSRN is used to identify either the recipient or individual provider of services in the context of a service relationship. In order to provide identification for both roles in a service relationship, recipient and provider, two GSRN AIs are available. The resultant element string provides a means for the service provider to store data relevant to services provided to the recipient and by the individual provider.

The GS1 Company Prefix is allocated by GS1 Member Organisations to the company that allocates the GSRN – here the organisation offering the service (see section 1.2.3.3). It makes the number unique worldwide.

The structure and content of the service reference is at the discretion of the organisation offering the service in order to uniquely identify each service relation.

The check digit is explained in section 7.9. Its verification, which must be carried out in the application software, ensures that the number is correctly composed.

The Global Service Relation Number – Provider (see figure below) identifies the relationship between an organisation offering services and the provider of services.

GS1 Application Identifier	Global Service Relation Number (GSRN) - PROVIDER	
	GS1 Company Prefix → ← Service reference	Check digit
8 0 1 7	N_1 N_2 N_3 N_4 N_5 N_6 N_7 N_8 N_9 N_{10} N_{11} N_{12} N_{13} N_{14} N_{15} N_{16} N_{17}	N_{18}

The data transmitted from the barcode reader means that the element string denoting the Global Service Relation Number for the Provider has been captured.