The Global Language of Business

GSMP:

General Specifications Change Notification (GSCN)

WR #	GSCN Name	Effective Date
24-296	Remove use of GTIN-8 with AI (03)	DD-MM-YYYY

Associated Work Request (WR) Number:

Insert the associated WR number here (if applicable)
WR 21-283

Background:

Insert background Information Here
WR 21-283 incorrectly implied that GTIN-8 could be used with AI (03). This work request has corrected this

Disclaimer

GS1 General Specification Change:

- See changes on next page – changes related to WR 24-296 are shown with comments.

Attributes

Required

AI (8030) Digital Signature (DigSig)

Instance level identification is required in addition to AI (8030), see Table 4-1 Entities identified by GS1 identification keys (simple or compound) within the GS1 System Architecture document.

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

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)

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Application description

MUDI-DI meets a EUDAMED registration requirement for highly individualised medical devices. The first published regulatory requirement covers contact lenses, per both Mmade-to-sStock (standard contact lenses per regulation (EU) 2017/745 as amended 7 October, 2023) and mMade-to-oOrder contact lenses. Future regulation may cover additional device types. MUDI-DI permits consolidated EUDAMED registration of standard contact lenses with similar clinical 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. 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 Mmade-to-sStock

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 Mmade-to-Sstock contact lenses in the EU.

- For Mmade-to-Oorder devices where GTIN is not currently used, a Mmade-to-Oorder GTIN willSHALL be used in conjunction with a compound key component (e.g., lot number, serial number). This GTIN willSHALL be used as the MUDI-DI and therefore the UDI-DI. This GTIN willSHALL be qualified using AI (03) not AI (01) to signal scanning/reading systems that the compound GTIN key is required and that the GTIN itself is allocated according to Mmade-to-Oorder GTIN rules rather than the current Mmade-to-Sstock rules. This GTIN may be a GTIN-8, 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 Mmade-to-Oorder GTIN, once assigned, SHALL NOT be reissued.

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 (Mmade-to-Sstock) GS1 Healthcare GTIN Allocation Rules StandardGTIN allocation rules

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

For Mmade-to-Oorder devices not currently identified by a GTIN:

- Made-to-Oorder GTIN SHALL be used as the MUDI-DI (UDI-DI)
- Made-to-Oorder GTIN in conjunction with a compound 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 GTIN allocation rules used for Mmade-to-Sstock products, GTIN willSHALL 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 Mmade-to-Sstock 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 Mmade-to-sStock 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 sSection 2.6.13.
- Allocation of the Highly Individualised Device Registration Identifier (HIDRI) to register a family of Mmade-to-Sstock contact lenses as the MUDI-DI is made per the discretion of the brand

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owner, but in compliance with EU regulatory requirements based on the EU Medical Device Regulation (MDR).

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

- The Mmade-to-Oorder GTIN SHALL be used as a Global Trade Item Number (GTIN) in conjunction with a compound GTIN key component (e.g., lot number, serial number) in order to create a unique trade item identifier.
- The Mmade-to-oOrder 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 Mmade-to-Oorder GTIN for a family of Mmade-to-Oorder contact lenses is made per the discretion of the brand owner, but in compliance with EU regulatory requirements based on the EU Medical Device Regulation (MDR).
- The same GTIN value SHALL NOT be used with AI (01) and AI (03).

Attributes

Required

Where one Mmade-to-Oorder 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 similar characteristics, in the context of the EU UDI requirements for contact lens, there SHALL BE:

a. ~~a)~~ no requirement to conform to the existing GS1 Healthcare GTIN Allocation Rules Standard ~~GTIN allocation rules~~ and

b. ~~b)~~ 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.

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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 lens 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:

a. ~~a)~~ no requirement to conform to existing GS1 Healthcare GTIN Allocation Rules Standard ~~GTIN allocation rules~~ and:

b. ~~b)~~ GTIN with another compound key data 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 ~~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 2.7.1 below provide relevant application standards.

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

Symbol placement

All the symbol placement guidelines defined in section ~~6~~6.

Unique application processing requirements

For a description of processing requirements, see section 7.

2.7 Summary of applications and operative scanning environments

The figure below 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 5.12.2.6-2 to determine the correct symbol specification table.

Figure 2.7-1. 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
Serial publications scanned at retail POS using ISSN, GTIN-13, or GTIN-12	2.1.3.5	1
Fixed measure fresh food trade items scanned at retail POS	2.1.3.6	1
Fixed measure trade items scanned in general distribution and at retail POS	2.1.4	3
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
Fixed measure trade items scanned in general distribution	2.1.7	2
Regulated healthcare trade items	2.1.7	8

The data transmitted from the barcode reader means that the element string denoting the GTIN of a trade item has been captured.

When indicating this element string in the non-HRI text section of a barcode label, the following data title SHOULD be used: **GTIN**

3.3.3 Identification of trade items contained in a logistic unit: AI (02)

The GS1 Application Identifier (02) indicates that the GS1 Application Identifier data field includes the GTIN of the contained trade items. The GTIN is used to identify trade items (see section 4).

The GTIN for trade items may be a GTIN-8, GTIN-12, GTIN-13 or a GTIN-14. See section 2 for the rules for GTIN formats and mandatory or optional attributes in the various trade item applications.

The GTIN of the trade items contained is the GTIN of the highest level of trade item contained in the logistic unit.

Note: This element string SHALL be used only on a logistic unit if:

- the logistic unit is not itself a trade item; and
- all trade items that are contained at the highest level have the same GTIN.

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.

Figure 3.3.3-1. Format of the element string

	GS1 Application Identifier	Global Trade Item Number (GTIN)													
		GS1-8 Prefix or GS1 Company Prefix →								← Item reference					Check digit
(GTIN-8)	0 2	0	0	0	0	0	0	N_1	N_2	N_3	N_4	N_5	N_6	N_7	N_8
(GTIN-12)	0 2	0	0	N_1	N_2	N_3	N_4	N_5	N_6	N_7	N_8	N_9	N_{10}	N_{11}	N_{12}
(GTIN-13)	0 2	0	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}
(GTIN-14)	0 2	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}

The data transmitted from the barcode reader means that the element string denoting the GTIN of trade items contained in a logistic unit has been captured.

This element string must be processed together with the count of trade items, AI (37), which must appear on the same unit (see section 3.6.5). Restrictions apply to the use of AI (02) in combination with other AIs, see section 4.13 *Data relationships.*

When indicating this element string in the non-HRI text section of a barcode label, the following data title SHOULD be used: **CONTENT**

3.3.4 Identification of a Made-to-Order (MtO) trade item (GTIN): AI (03)

The GS1 Application Identifier (03) indicates that the GS1 Application Identifier data field contains an Identification of a Made-to-Order (MtO) trade item (GTIN). The Identification of a Made-to-Order (MtO) trade item (GTIN) is used to identify trade items (see section 2.6.17). This GTIN may be a ~~GTIN-8,~~ GTIN-12, GTIN-13 or a GTIN-14, see section 2.6.17~~6.17~~ for the rules for GTIN formats and mandatory or optional attributes in the various trade item applications.

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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.

Figure 3.3.4-1. Format of the element string

	GS1 Application Identifier	Identification of a Made-to-Order (MtO) trade item (GTIN)													
		GS1 8 Prefix or GS1 Company Prefix ——>									Item reference <——				Check digit
(GTIN-8)	0 3	0	0	0	0	0	0	N_1	N_2	N_3	N_4	N_5	N_6	N_7	N_8
(GTIN-12)	0 3	0	0	N_1	N_2	N_3	N_4	N_5	N_6	N_7	N_8	N_9	N_{10}	N_{11}	N_{12}
(GTIN-13)	0 3	0	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}
(GTIN-14)	0 3	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}

NOTE: GTIN-8 (see section 4.2.7) is not an option for Made-to-Order GTIN.

The data transmitted from the barcode reader means that the element string denoting the GTIN of a Made-to-Order trade item has been captured.

When indicating this element string in the non-HRI text section of a barcode label, the following data title SHOULD be used: **MTO GTIN**

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3.4 GS1 Application Identifiers starting with digit 1

3.4.1 Batch or lot number: AI (10)

The GS1 Application Identifier (10) indicates that the GS1 Application Identifier data field contains a batch or lot number. The batch or lot number associates an item with information the manufacturer considers relevant for traceability of the trade item to which the element string is applied. The data may refer to the trade item itself or to items contained. The number may be, for example, a production lot number, a shift number, a machine number, a time, or an internal production code. In cases where the same product is manufactured in different locations the brand owner and the manufacturer are responsible for ensuring the non-duplication of batch/lot numbers for a GTIN. For the re-use of batch/lot numbers with a GTIN, sector-specific constraints need to be considered.

The data is alphanumeric and may include all characters contained in figure 7.11-1.

Note: The batch or lot number is not part of the unique identification of a trade item.

Figure 3.4.1-1. Format of the element string

GS1 Application Identifier	Batch or lot number
1 0	X_1 ——> variable length ——> X_{20}

The data transmitted by the barcode reader means that the element string denoting a batch or lot number has been captured. As this element string is an attribute of a particular item, it must be processed together with the GTIN of the trade item to which it relates (see section 4.13.2). When indicating this element string in the non-HRI text section of a barcode label, the following data title SHOULD be used: **BATCH/LOT**

3.4.2 Production date: AI (11)

The GS1 Application Identifier (11) indicates that the GS1 Application Identifier data field contains a production date. The production date is the production or assembly date determined by the manufacturer. The date may refer to the trade item itself or to items contained. The structure is:

- Year: the tens and units of the year (e.g., 2003 = 03), which is mandatory.
- Month: the number of the month (e.g., January = 01), which is mandatory.
- Day: the number of the day of the relevant month (e.g., second day = 02); if it is not necessary to specify the day, the field must be filled with two zeroes.

Term	Definition
Made-to-Order (MtO) trade item	A bespoke (e.g., customised, personalised, configurable) product or service where the GTIN, allocated per application specific rules rather than the GTIN Management Standard, plus a compound key data element (Mmade-to-Oorder variant, lot number, serial number) is required to distinguish whenever any of the trade item declarations are different in any way that is relevant to the trading process.
Made-to-Stock (MtS) trade item	A product or service where a separate, unique GTIN, allocated per the GTIN Management Standard, is required to distinguish whenever any of the trade item declarations are different in any way that is relevant to the trading process.
main symbol	The barcode containing the identification number of the item (e.g., GTIN, SSCC). Used to determine the placement of any additional barcode information.
Master Unique Device Identifier – Device Identifier (MUDI-DI)	The Master UDI-DI is a unique identifier specific to a family of highly individualised medical devices for the restricted use of EUDAMED registration.
measure verifier digit	A digit calculated from the measure field in a Restricted Circulation Number (RCN) that is used to check that the data has been correctly composed.
Medical device family	A group of medical devices manufactured by or for the same organization and have the same basic design and performance characteristics related to safety, intended use and function.* ***SOURCE**: ISO 13485- Medical devices - Quality management systems – Requirements for regulatory purposes.
merchant	The party that makes a trade item available for sale. A retailer is one type of merchant. An online seller is another type of merchant.
model reference	A component of the Global Model Number (GMN) assigned by the brand owner to create a unique GMN.
module	The narrowest nominal width unit of measure in a barcode. In certain symbologies, element widths may be specified as multiples of one module. The nominal width (& height for 2D barcodes) of a single module is equivalent to the X-dimension.
modulo 10	The name of the algorithm – a simple checksum formula in the public domain – used to create a check digit for those GS1 identification keys that require one.
multiple unit blister/package	Immediate package for a medicine with more than one single unit. Package which fully encloses the pill/caplet/capsule. Each dosage form may be individually packaged. The individually blistered dosage forms are attached to each other in one strip.
National Healthcare Reimbursement Number (NHRN)	National and/or regional identification numbers used on pharmaceutical and/or medical devices where required by national or regional regulatory organisations for product registration purposes and/or for the management of healthcare provider reimbursement.
National Trade Item Number (NTIN)	A coding scheme, administered in the healthcare sector by a national organisation for which a GS1 Prefix has been issued to permit its uniqueness within the GTIN pool but without assurance of full compatibility with GTIN functionality. The result is a product identification number assigned by a third party (not the brand owner or manufacturer). Example: the CIP (Club Inter Pharmaceutique) in France administered by the French Health Products Safety Agency (AFSSAPS).
non-human readable interpretation text (non-HRI)	Characters such as letters and numbers that can be read by persons and may or may not be encoded in GS1 AIDC data carriers and are not confined to a structure and format based on GS1 standards (e.g., a date code expressed in a national format that could be used to encode a date field in a GS1 AIDC data carrier, brand owner name, consumer declarations).
odd parity	A characteristic of the encodation of a symbol character whereby the symbol character contains an odd number of dark modules.
offer declarations	The set of all information declared (or agreed to) by the seller about the trade item (inclusive of price, availability, terms of sale, claims, condition, shipping information, returns information, etc).
omnidirectional linear barcode	A linear barcode symbology designed to be read in segments by suitably programmed laser point-of-sale (POS) scanners.
packaging component	Objects such as bottles, caps and labels to package a consumer trade item.
packaging component number	Global Trade Item Number (GTIN) attribute used to establish a relationship between a finished consumer trade item and packaging components.
payment slip	The end customer's notification of a demand for payment for a billable service (e.g., utility bill) comprising an amount payable and payment conditions.

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