



General Specifications Change Notification (GSCN)

WR #	GSCN Name	Effective Date
WR-21-283	AIDC Application Standard Master UDI-DI for registration of certain type of devices within EUDAMED	May 2024

Associated Work Request (WR) Number:

N/A

Background:

The European (EU) Commission requires the development of a "M-UDI" for implementation of a new level of eyewear product identification for standard contact lenses as part of the UDI requirements based on the European Union Medical Device Regulation (MDR). 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.

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 "M-UDI". GS1 is the most often used identification system for UDI implementation and as such, our users expect GS1 to offer an appropriate identifier to implement the "M-UDI". Internal analysis of the GS1 standards for identification has concluded that M-UDI requirements would be met by a Global Model Number – M-UDI with a different GS1 Application Identifier from the multi-sector GMN, B-UDI for the healthcare sector. The European Commission will, by means of tertiary legislation as deemed necessary, specify the necessary elements concerning the UDI assignment to highly individualised products.

As a Designated EU issuing entity for UDI, GS1 must develop specifications and rules for the "M-UDI" 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 standard contact lenses needs to be developed to allow grouped reporting of UDI-DI (i.e., GTIN) data to EUDAMED.

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GS1 General Specification Change:

Changes to the following sections:

2 Application standards

2.6 Special applications

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 covers 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. 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 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 in the EU.
- For made-to-order devices where GTIN is not currently used, a made-to-order GTIN will be used in conjunction with a compound key component (e.g., lot number, serial number). This GTIN will be used as the MUDI-DI and therefore the UDI-DI. This GTIN will 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 made-to-order GTIN rules rather than the current made-to-stock 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 made-to-order 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 (made-to-stock) GTIN 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 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 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)

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Rules

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See section 4.13

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For devices using current GTIN allocation rules used for made-to-stock products, GTIN will 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:

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- 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.

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- 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).

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- 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.

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- 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.

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- In documentation, the MUDI-DI shall be displayed per GMN rules found in Section 2.6.13

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- Allocation of the Highly Individualised Device Registration Identifier (HIDRI) to register a family of made-to-stock contact lenses 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).

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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:

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- The made-to-order 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.

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- The made-to-order GTIN SHALL be used for EUDAMED registration purposes as the MUDI-DI (UDI-DI).

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- 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.

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- Allocation of the made-to-order GTIN for a family of made-to-order 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).

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- The same GTIN value SHALL NOT be used with AI (01) and AI (03).

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Attributes

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Required

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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 similar characteristics, in the context of the EU UDI requirements for contact lens, there SHALL BE:

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a) no requirement to conform to the existing GTIN allocation rules and

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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) no requirement to conform to existing GTIN allocation rules and:
- 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 - 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.

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](#).

140 **3.2 GS1 Application Identifiers in numerical order**

141 **Figure 3.2 1.** GS1 Application Identifiers

AI	Data Content	Format ⁽¹⁾	FNC1 required ⁽⁴⁾	Data title
00	Identification of a logistic unit (SSCC): AI (00)	N2+N18		SSCC
01	Identification of a trade item (GTIN): AI (01)	N2+N14		GTIN
02	Identification of trade items contained in a logistic unit: AI (02)	N2+N14		CONTENT
03	Identification of a Made-to-Order (MtO) trade item (GTIN): AI (03)	N2+N14		MTO GTIN
10	Batch or lot number: AI (10)	N2+X..20	(FNC1)	BATCH/LOT
11 ⁽²⁾	Production date: AI (11)	N2+N6		PROD DATE
12 ⁽²⁾	Due date for amount on payment slip: AI (12)	N2+N6		DUE DATE
13 ⁽²⁾	Packaging date: AI (13)	N2+N6		PACK DATE
15 ⁽²⁾	Best before date: AI (15)	N2+N6		BEST BEFORE or BEST BY
16 ⁽²⁾	Sell by date: AI (16)	N2+N6		SELL BY
17 ⁽²⁾	Expiration date: AI (17)	N2+N6		USE BY OR EXPIRY
20	Internal product variant: AI (20)	N2+N2		VARIANT
21	Serial number: AI (21)	N2+X..20	(FNC1)	SERIAL
22	Consumer product variant: AI (22)	N2+X..20	(FNC1)	CPV
235	Third Party Controlled, Serialised Extension of Global Trade Item Number (GTIN) (TPX): AI (235)	N3+X..28	(FNC1)	TPX
240	Additional product identification assigned by the manufacturer: AI (240)	N3+X..30	(FNC1)	ADDITIONAL ID
241	Customer part number: AI (241)	N3+X..30	(FNC1)	CUST. PART No.
242	Made-to-Order variation number: AI (242)	N3+N..6	(FNC1)	MTO VARIANT
243	Packaging component number: AI (243)	N3+X..20	(FNC1)	PCN
250	Secondary serial number: AI (250)	N3+X..30	(FNC1)	SECONDARY SERIAL
251	Reference to source entity: AI (251)	N3+X..30	(FNC1)	REF. TO SOURCE
7240	Protocol ID: AI (7240)	N4+X..20	(FNC1)	PROTOCOL
7241	Error! Reference source not found.	N4+N2	(FNC1)	AIDC MEDIA TYPE
7242	Error! Reference source not found.	N4+X..25	(FNC1)	VCN
8001	Roll products - width, length, core diameter, direction, splices: AI (8001)	N4+N14	(FNC1)	DIMENSIONS
8002	Cellular mobile telephone identifier: AI (8002)	N4+X..20	(FNC1)	CMT No.
8003	Global Returnable Asset Identifier (GRAI): AI (8003)	N4+N14[+X..16]	(FNC1)	GRAI
8004	Global Individual Asset Identifier (GIAI): AI (8004)	N4+X..30	(FNC1)	GIAI
8005	Price per unit of measure: AI (8005)	N4+N6	(FNC1)	PRICE PER UNIT
8006	Identification of an individual trade item (ITIP) piece: AI (8006)	N4+N14+N2+N2	(FNC1)	ITIP
8007	International Bank Account Number (IBAN): AI (8007)	N4+X..34	(FNC1)	IBAN
8008	Date and time of production: AI (8008)	N4+N8[+N..4]	(FNC1)	PROD TIME
8009	Optically readable sensor indicator: AI (8009)	N4+X..50	(FNC1)	OPTSEN
8010	Component/Part Identifier (CPID): AI (8010)	N4+Y..30	(FNC1)	CPID
8011	Component/Part Identifier serial number: AI (8011)	N4+N..12	(FNC1)	CPID SERIAL

AI	Data Content	Format ⁽¹⁾	FNC1 required ⁽⁴⁾	Data title
8012	Software version: AI (8012)	N4+X..20	(FNC1)	VERSION
8013	Global Model Number (GMN): AI (8013)	N4+X..25	(FNC1)	GMN
8014	Highly Individualised Device Registration Identifier (HIDRI): AI (8014)	N4+X..25	(FNC1)	MUDI
8017	Global Service Relation Number (GSRN) to identify the relationship between an organisation offering services and the provider of services: AI (8017)	N4+N18	(FNC1)	GSRN - PROVIDER

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<p>NOTES:</p> <p>(1): The first position indicates the length (number of digits) of the GS1 Application Identifier. The following value refers to the format of the data content. The following convention is applied:</p> <ul style="list-style-type: none"> ▪ n implied decimal point position ▪ N numeric digit ▪ X any character in figure 7.11-1 for GS1 AI encodable character set 82 ▪ Y any character in figure 7.11-2 for GS1 AI encodable character set 39 ▪ Z any character in figure Error! Reference source not found.-3 for GS1 AI encodable character set 64 (file-safe / URI-safe base64) ▪ N2 2 numeric digits, fixed length ▪ N3 3 numeric digits, fixed length ▪ N4 4 numeric digits, fixed length ▪ X3 3 characters, fixed length ▪ N..3 up to 3 numeric digits ▪ X..3 up to 3 characters in figure 7.11-1 for GS1 AI encodable character set 82 ▪ Y..3 up to 3 characters in figure 7.11-2 for GS1 AI encodable character set 39 ▪ Z..3 up to 3 characters in figure Error! Reference source not found.-3 for GS1 AI encodable character set 64 (file-safe / URI-safe base64) ▪ [] enclosed value is an optional component <p>(2): If only year and month are available, DD must be filled with two zeroes, except where noted.</p> <p>(3): The fourth digit of this GS1 Application Identifier indicates the number of decimal places (and in that way the implied decimal point position). Example:</p> <ul style="list-style-type: none"> ▪ 3100 Net weight in kg without a decimal point ▪ 3102 Net weight in kg with two decimal places <p>see section Error! Reference source not found. for further information.</p> <p>(4): All GS1 element strings that begin with GS1 Application Identifiers not contained in the predefined table shown in figure 7.8.5-2 SHALL be separated by a separator character unless this element string is the last one to be encoded in the symbol. For details on the separator character see section 7.8.4.</p> <p>(5) An example to illustrate future additional National Healthcare Reimbursement Numbers (NHRNs). If additional NHRN AIs are required, a request for a new NHRN AI SHALL be made through GSMP.</p> <p>(6) The fourth digit of this GS1 Application Identifier indicates the sequence number, allowing for multiple occurrences of the AI.</p> <p>(7) The temperatures in these GS1 Application Identifiers are expressed in hundredths of degrees.</p>
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146 **3.3 GS1 Application Identifiers starting with digit 0**

147 **3.3.4 Identification of a Made-to-Order (MtO) trade item (GTIN): AI (03)**

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

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

155 **Figure 3.3.4-1.** Format of the element string

	GS1 Application Identifier	Identification of a Made-to-Order (MtO) trade item (GTIN)												Check digit	
		GS1-8 Prefix or GS1 Company Prefix →						← Item reference							
(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

157 The data transmitted from the barcode reader means that the element string denoting the GTIN of a
 158 Made-to-Order trade item has been captured.
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160 When indicating this element string in the non-HRI text section of a barcode label, the following data
 161 title SHOULD be used: **MTO GTIN**

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 163 **3.8 GS1 Application Identifiers starting with digit 8**

164 **3.9.14 Highly Individualised Device Registration Identifier (HIDRI): AI (8014)**

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

170 The structure and content of the grouping reference are at the discretion of the brand owner. It may
 171 contain all characters listed in figure 7.11-1.

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

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

177 **Figure 3.8.22-1** Format of the element string

GS1 Application Identifier	Highly Individualised Device Registration Identifier (HIDRI)				Check characters
	GS1 Company Prefix →		Grouping reference →		
8 0 1 4	N ₁ ...	N _i	X _{i+1} ...	variable length	X _{j (j<=23)}

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

180 **Note:** This element string SHALL never be used to identify the entity as a trade item. The
 181 GS1 Company Prefix (see section 1.4.4) is allocated by GS1 Member Organisations to the
 182 brand owner that allocates the MUDI-DI. It makes the number unique worldwide. The MUDI-
 183 DI can be used in any labelling, physical marking, or GS1 AIDC data carrier on associated
 184 trade items. For the purpose of EUDAMED access, HIDRI is sufficient as a standalone key.
 185 When used in a barcode with production identifiers (e.g., lot number, serial number), HIDRI
 186 shall be associated with GTIN as the Application Identifiers for production identifiers have a
 187 mandatory association with GTIN

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

191 **4.13.1 Invalid pairs of element strings**

192 This section defines the pairs of element strings that SHALL NOT appear together on the same
 193 physical entity. The table does not provide a finite list of all possible rules, only situations that have
 194 proven to pose difficulties in practice are included.

195 Some explanation on figure [4.13.1-1](#):

- 196 ■ The table is sorted by AI value, with the lowest AI value displayed in the first column.
- 197 ■ Multiple AIs may be listed in the first or third column, separated by commas. This means that
 198 the same rule applies to all listed AIs.
- 199 ■ The rules work in both directions, e.g., if it states AI (01) SHALL NOT be combined with AI (37)
 200 this implies that AI (37) SHALL NOT be combined with AI (01).
- 201 ■ For the purpose of this table Made-to-Stock (MtS) GTIN AI (01) and Made-to-Order (MtO) GTIN
 202 AI (03) are simply referred to as GTIN.

203 **Figure 4.13.1-1.** Invalid pairs of element strings


Invalid pairs of element strings				Rule
AI	Designation	AI	Designation	
01	GTIN	01	GTIN	All occurrences of GTIN SHALL have one value. It is for example not allowed to include GTINs of other packaging levels.
01	GTIN	02	GTIN of contained trade items	GTIN of contained trade items is intended to list the trade items contained in a logistic unit and SHALL NOT be used to identify the contents of a trade item.
01	GTIN	03	GTIN	The same GTIN value SHALL NOT be used with AI (01) and AI (03) and a trade item identified with (01) GTIN SHALL not be identified by a MtO GTIN with AI (03).
01, 03	GTIN	37	Count of units contained	The count of units contained SHALL only be used with GTIN of contained trade items or trade item pieces.
01	GTIN	255	Global Coupon Number	A trade item SHALL NOT also be identified as a coupon.
03	GTIN	02	GTIN of contained trade items	GTIN of contained trade items is intended to list the trade items contained in a logistic unit and SHALL NOT be used to identify the contents of a MtO trade item.

Invalid pairs of element strings				Rule
AI	Designation	AI	Designation	
21	Serial Number	235	Third Party Controlled, Serialised Extension of GTIN	Only Serial Number or Third Party Controlled, Serialised Extension of GTIN SHALL be used with GTIN.

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206 **4.13.2 Mandatory association of element strings**

207 This section defines the element strings that mandate the appearance of another element string on
 208 the same physical entity.

209  **Note:** This does not necessarily mean that the element strings need to appear in the same
 210 data carrier. For example, multiple GS1-128 barcode symbols may be used in combination on
 211 a GS1 Logistic Label.

212 The figure below reflects the use case requirements to date. Should future applications arise that
 213 require associations they will be added at that time.

214 Some explanation on figure [4.13.2-1](#):

- 215 ■ The table is sorted by AI value, with the AI that is the trigger for the rule displayed in the first
 216 column. This means that this table cannot be read in both directions. For example, a rule that
 217 states AI (17) must be used together with AI (01), does not imply that AI (01) can only be used
 218 together with AI (17), since it can also be used with other AIs.
- 219 ■ Multiple AIs may be listed in the first column, separated by commas. This means that the rule
 220 applies to all of the listed AIs (element strings).
- 221 ■ The same AI can occur in the first column multiple times, in different rows. This means that
 222 depending on the value of the element string different rules need to be applied.
- 223 ■ When multiple AIs are included in the third column, this is always done with an AND, OR or XOR
 224 logical operator between them:
 - 225 □ AND means that all element strings SHALL appear on the physical entity
 - 226 □ OR means that one or a combination of the element strings SHALL appear on the physical
 227 entity.
 - 228 □ XOR means that one of the element strings SHALL appear on the physical entity and the
 229 other element string SHALL NOT.

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231 **Figure 4.13.2-1.** Mandatory association of element strings

If element string		Then mandatory associated element string	Rule
AI	Designation	AI	
01 with N ₁ = 0	GTIN of a variable measure trade item scanned at POS	30 OR 3nnn*	The GTIN of a variable measure trade item scanned at POS SHALL occur in combination with: <ul style="list-style-type: none"> ■ variable count of items; or ■ a trade measure Note: Master data will be needed to determine whether the GTIN represents a variable measure trade item scanned at POS. Also see the note below this table.

If element string		Then mandatory associated element string	Rule
AI	Designation	AI	
01 with N ₁ = 9, 02 with N ₁ = 9	GTIN of a variable measure trade item not scanned at POS	30 OR 3nnn* OR 8001	The GTIN of a variable measure trade item not scanned at POS SHALL occur in combination with: <ul style="list-style-type: none"> variable count of items; or a trade measure; or the dimensions of a roll product. Note: The first position of the GTIN is "9" for such trade items. Also see the note below this table.
01 with N ₁ = 9 or 03	Made to Order Variation Number AI (242)	GTIN of a custom trade item per Section 2.6.8 or Made-to-Order GTIN (03)	The GTIN of a custom trade item using AI (01) and indicator digit "9" SHALL be used in combination with the Made-to-Order variation number. Note: The first position of the GTIN is "9" for such trade items. The Made-to-Order variation number MAY also be used with Made-to-Order GTIN using AI (03).
02	GTIN of contained trade items	00 AND 37	The GTIN of contained trade items SHALL occur in combination with an SSCC and the count of the trade items.
10	Batch/lot number	01 XOR 02 XOR 8006 XOR 8026 XOR 03 ***	Batch/lot number SHALL occur in combination with: <ul style="list-style-type: none"> a GTIN; or a GTIN of contained trade items; or Identification of a Made-to-Order (MtO) trade item (GTIN; or an ITIP an ITIP of contained trade item pieces
11, 13, 15, 16, 17	Production date, packaging date, best before date, sell by date, expiration date (of a trade item)	01 XOR 02 XOR 8006 XOR 8026 ***	These dates SHALL occur in combination with: <ul style="list-style-type: none"> a GTIN; or a GTIN of contained trade items; or an ITIP an ITIP of contained trade item pieces
21	Serial number	01 XOR 03 XOR 8006***	The serial number SHALL occur in combination with: <ul style="list-style-type: none"> a GTIN; or Identification of a Made-to-Order (MtO) trade item (GTIN);or an ITIP Note: SGTIN is a common term for the combination of GTIN and serial number.
8014	Highly Individualised Device Registration Identifier (HIDRI)	01	Highly Individualised Device Registration Identifier SHALL occur in combination with: <ul style="list-style-type: none"> a GTIN with AI (01)

232 **9 GS1 Standards glossary of terms**

233 **9.1 GS1 glossary of terms and definitions**

234 The glossary lists the terms and definitions that are applied in this document. Please refer to the
235 www.gs1.org/glossary for the online version.
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Term	Definition
Basic Unique Device Identifier – Device Identifier (UDI-DI)	The Basic UDI - DI is a unique identifier specific to a medical device product model . It is represented by GS1’s Basic-UDI- DI Global Model Number (B-UDI - GMN).
compound key	Two or more data elements which together serve as a key, where no subset of those data elements taken by themselves would do so (also see simple key).
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.
standard contact lenses (per EU MDR)	A type of highly individualised device, (typically made-to-stock and identified by GTIN for trade purposes), registered in EUDAMED per European Medical Device Regulations (MDR)
EUDAMED	European database on medical devices (EUDAMED) https://ec.europa.eu/health/medical-devices-eudamed/overview_en
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 (made-to-order 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.
Highly Individualised Device (per EU MDR)	Device subject to EUDAMED registration via MUDI-DI as UDI-DI
Highly Individualised Device Registration Identifier (HIDRI)	A special version of the Global Model Number that identifies a group of highly individualised medical devices within EUDAMED.
simple key	A single data element that serves as a key (also see compound key).

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239 **9.3 GS1 abbreviations**

Abbreviation	Term
MtO	Made-to-Order
MtS	Made-to-Stock
HIDRI	Highly Individualised Device Registration Identifier

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