



## 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	DD-MM-YYYY

### 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.

### Disclaimer:

GS1®, under its IP Policy, seeks to avoid uncertainty regarding intellectual property claims by requiring the participants in the Work Group that developed this **General Specifications Change Notification** to agree to grant to GS1 members a royalty-free licence or a RAND licence to Necessary Claims, as that term is defined in the GS1 IP Policy. Furthermore, attention is drawn to the possibility that an implementation of one or more features of this Specification may be the subject of a patent or other intellectual property right that does not involve a Necessary Claim. Any such patent or other intellectual property right is not subject to the licensing obligations of GS1. Moreover, the agreement to grant licences provided under the GS1 IP Policy does not include IP rights and any claims of third parties who were not participants in the Work Group.

Accordingly, GS1 recommends that any organisation developing an implementation designed to be in conformance with this Specification should determine whether there are any patents that may encompass a specific implementation that the organisation is developing in compliance with the Specification and whether a licence under a patent or other intellectual property right is needed. Such a determination of a need for licensing should be made in view of the details of the specific system designed by the organisation in consultation with their own patent counsel.

THIS DOCUMENT IS PROVIDED "AS IS" WITH NO WARRANTIES WHATSOEVER, INCLUDING ANY WARRANTY OF MERCHANTABILITY, NONINFRINGEMENT, FITNESS FOR PARTICULAR PURPOSE, OR ANY WARRANTY OTHERWISE ARISING OUT OF THIS DOCUMENT. GS1 disclaims all liability for any damages arising from use or misuse of this document, whether special, indirect, consequential, or compensatory damages, and including liability for infringement of any intellectual property rights, relating to use of information in or reliance upon this document.

GS1 retains the right to make changes to this document at any time, without notice. GS1 makes no warranty for the use of this document and assumes no responsibility for any errors which may appear in the document, nor does it make a commitment to update the information contained herein.

GS1 and the GS1 logo are registered trademarks of GS1 AISBL.

## GS1 General Specification Change:

Changes to the following sections:

## 2 Application standards

### 2.6 Special applications

#### 2.6.17 Restricted Application - Highly Individualised Device Registration Identifier via MUDI-DI

##### Application description

MUDI-DI meets a EUDAMED registration requirement for highly individualised medical devices. The first published regulatory requirement covers standard contact lens, both made-to-stock and made-to-order. 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, will continue to be used for these devices to support current business processes.
- 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 component (e.g., lot number, serial number) SHALL be used for current business processes)

##### Rules

See section **Error! Reference source not found.**

46 For devices using current GTIN allocation rules used for made-to-stock products, GTIN will continue  
47 to be used for current business processes and the Highly Individualised Device Registration  
48 Identifier (HIDRI) SHALL be used as the MUDI-DI (UDI-DI) according to the following rules:

- 49 ■ The Highly Individualised Device Registration Identifier (HIDRI) SHALL be used as MUDI-DI and  
50 SHALL NOT be used to identify the device for the purpose of trade where Global Trade Item  
51 Number (GTIN) is used today.
- 52 ■ The GTIN SHALL NOT be used for MUDI-DI registration purposes where the Highly Individualised  
53 Device Registration Identifier (HIDRI) serves as the MUDI-DI (UDI-DI).
- 54 ■ At any given time, the relationship between the Highly Individualised Device Registration  
55 Identifier (HIDRI) / (MUDI-DI) and a made-to-stock GTIN using AI (01) is 1:n (can be one to  
56 one or one to many), meaning the Highly Individualised Device Registration Identifier (HIDRI) /  
57 (MUDI-DI) can be related to more than one made-to- stock GTIN.
- 58 ■ The Highly Individualised Device Registration Identifier (HIDRI) implementation of GMN SHALL  
59 contain at least one non-numeric character between the GS1 Company Prefix and the check  
60 character pair. This is required as the Highly Individualised Device Registration Identifier  
61 (HIDRI) will be stored in the same EUDAMED field as GTIN. This restricted use of GS1's Global  
62 Model Number SHALL therefore have the same format as GMN but the addition of this rule is  
63 necessary to eliminate any possible overlap of GMN and GTIN in the same EUDAMED field.
- 64 ■ In documentation, the MUDI-DI shall be displayed as a single data field, but formatting such as  
65 bold or italics may be used within text representation of the identifier to increase efficiency and  
66 accuracy of key-entry. Spaces are not permitted as characters in the MUDI-DI when encoded in  
67 the AIDC data carrier, but may appear in human-readable text.
- 68 ■ Allocation of the Highly Individualised Device Registration Identifier (HIDRI) to register a family  
69 of made-to-stock contact lenses as an MUDI-DI is made per the discretion of the brand owner,  
70 but in compliance with EU regulatory requirements based on the EU Medical Device Regulation  
71 (MDR).

72  
73  
74  
75 For made-to-order devices not currently identified by a made-to-stock GTIN, a made-to-order GTIN  
76 SHALL be used as the MUDI-DI (UDI-DI) for EUDAMED registration according to the following rules:

- 77 ■ The made-to-order GTIN SHALL be used as a Global Trade Item Number (GTIN) in conjunction  
78 with a compound GTIN key component (e.g., lot number, serial number) in order to create a  
79 unique trade item identifier.
- 80 ■ The made-to-order GTIN SHALL be used for EUDAMED registration purposes as the MUDI-DI  
81 (UDI-DI).
- 82 ■ In documentation, the MUDI-DI shall be displayed as a single data field, but formatting such as  
83 bold or italics may be used within text representation of the identifier to increase efficiency and  
84 accuracy of key-entry.
- 85 ■ Allocation of the made-to-order GTIN for a family of made-to-order contact lenses is made per  
86 the discretion of the brand owner, but in compliance with EU regulatory requirements based on  
87 the EU Medical Device Regulation (MDR).

## 90 **Attributes**

### 91 **Required**

92 Where one made-to-order GTIN with AI (03) can support requirements related to specific use by a  
93 patient or the purpose of trade, intended use, or point-of-care and EUDAMED registration of highly  
94 individualised devices sharing similar characteristics, in the context of the EU UDI requirements for  
95 contact lens, there SHALL BE:

- 96 a) no requirement to conform to the existing GTIN allocation rules and
- 97 b) no mandatory requirement for LOT or SN (beyond that specified by regulation) to ensure  
98 unique identification.

99  
100  
101  
102  
103  
104  
105  
106  
107  
108  
109  
110  
111  
112  
113  
114  
115  
116  
117  
118  
119  
120  
121  
122  
123  
124  
125  
126

For contact lens registered using MUDI-DI in EUDAMED, where MUDI-DI is a MtO GTIN, and where the contact lens 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.

**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**

- GS1 DataMatrix

**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 device manufacturer. 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.

<u>Application</u>	<u>See section</u>	<u>SST(s)</u>	<u>Carrier choices</u>
<u>Healthcare primary packaging (non-retail trade items)</u>	<u>2.1.5</u>	<u>6</u>	<u>GS1-128, GS1 DataMatrix, GS1 DataBar, EAN/UPC, ITF- 14, Composite Component</u>
<u>Healthcare secondary packaging (regulated healthcare retail consumer trade items)</u>	<u>2.1.6</u>	<u>8 or 10</u>	<u>GS1-128, GS1 DataMatrix, GS1 DataBar, EAN/UPC, ITF-14, Composite Component</u>
<u>Fixed measure trade items scanned in general distribution, Regulated healthcare trade items</u>	<u>2.1.7</u>	<u>8</u>	<u>GS1-128, GS1 DataBar, GS1 DataMatrix, EAN/UPC, ITF-14 in accordance with Figure 2.1.7.1-2 Healthcare carrier choices</u>
<u>Medical devices (non-retail trade items)</u>	<u>2.1.8</u>	<u>7</u>	<u>GS1 DataMatrix</u>

**Symbol placement**

Not applicable.

**Unique application processing requirements**

For a description of processing requirements, see section 7.

**3.2 GS1 Application Identifiers in numerical order**

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

AI	Data Content	Format <sup>(1)</sup>	FNC1 required <sup>(4)</sup>	Data title
00	<a href="#">Identification of a logistic unit (SSCC): AI (00)</a>	N2+N18		SSCC
01	<a href="#">Identification of a trade item (GTIN): AI (01)</a>	N2+N14		GTIN
02	<a href="#">Identification of trade items contained in a logistic unit: AI (02)</a>	N2+N14		CONTENT
03	<a href="#">Identification of a made to order (MtO) trade item (GTIN): AI (03)</a>	<u>N2+N14</u>		<u>MTO GTIN</u>
10	<a href="#">Batch or lot number: AI (10)</a>	N2+X..20	(FNC1)	BATCH/LOT
11 <sup>(2)</sup>	<a href="#">Production date: AI (11)</a>	N2+N6		PROD DATE
12 <sup>(2)</sup>	<a href="#">Due date for amount on payment slip: AI (12)</a>	N2+N6		DUE DATE
13 <sup>(2)</sup>	<a href="#">Packaging date: AI (13)</a>	N2+N6		PACK DATE
15 <sup>(2)</sup>	<a href="#">Best before date: AI (15)</a>	N2+N6		BEST BEFORE or BEST BY
16 <sup>(2)</sup>	<a href="#">Sell by date: AI (16)</a>	N2+N6		SELL BY
17 <sup>(2)</sup>	<a href="#">Expiration date: AI (17)</a>	N2+N6		USE BY OR EXPIRY
20	<a href="#">Internal product variant: AI (20)</a>	N2+N2		VARIANT
21	<a href="#">Serial number: AI (21)</a>	N2+X..20	(FNC1)	SERIAL
22	<a href="#">Consumer product variant: AI (22)</a>	N2+X..20	(FNC1)	CPV
235	<a href="#">Third Party Controlled, Serialised Extension of Global Trade Item Number (GTIN) (TPX): AI (235)</a>	N3+X..28	(FNC1)	TPX
240	<a href="#">Additional product identification assigned by the manufacturer: AI (240)</a>	N3+X..30	(FNC1)	ADDITIONAL ID
241	<a href="#">Customer part number: AI (241)</a>	N3+X..30	(FNC1)	CUST. PART No.
242	<a href="#">Made-to-Order variation number: AI (242)</a>	N3+N..6	(FNC1)	MTO VARIANT
243	<a href="#">Packaging component number: AI (243)</a>	N3+X..20	(FNC1)	PCN
250	<a href="#">Secondary serial number: AI (250)</a>	N3+X..30	(FNC1)	SECONDARY SERIAL
251	<a href="#">Reference to source entity: AI (251)</a>	N3+X..30	(FNC1)	REF. TO SOURCE
7240	<a href="#">Protocol ID: AI (7240)</a>	N4+X..20	(FNC1)	PROTOCOL
7241	<del><a href="#">Error! Reference source not found. AIDC media type: AI (7241)</a></del>	N4+N2	(FNC1)	AIDC MEDIA TYPE
7242	<del><a href="#">Error! Reference source not found. Version Control Number (VCN): AI (7242)</a></del>	N4+X..25	(FNC1)	VCN
8001	<a href="#">Roll products - width, length, core diameter, direction, splices: AI (8001)</a>	N4+N14	(FNC1)	DIMENSIONS
8002	<a href="#">Cellular mobile telephone identifier: AI (8002)</a>	N4+X..20	(FNC1)	CMT No.

AI	Data Content	Format <sup>(1)</sup>	FNC1 required <sup>(4)</sup>	Data title
8003	<a href="#">Global Returnable Asset Identifier (GRAI): AI (8003)</a>	N4+N14[+X..16]	(FNC1)	GRAI
8004	<a href="#">Global Individual Asset Identifier (GIAI): AI (8004)</a>	N4+X..30	(FNC1)	GIAI
8005	<a href="#">Price per unit of measure: AI (8005)</a>	N4+N6	(FNC1)	PRICE PER UNIT
8006	<a href="#">Identification of an individual trade item (ITIP) piece: AI (8006)</a>	N4+N14+N2+N2	(FNC1)	ITIP
8007	<a href="#">International Bank Account Number (IBAN): AI (8007)</a>	N4+X..34	(FNC1)	IBAN
8008	<a href="#">Date and time of production: AI (8008)</a>	N4+N8[+N..4]	(FNC1)	PROD TIME
8009	<a href="#">Optically readable sensor indicator: AI (8009)</a>	N4+X..50	(FNC1)	OPTSEN
8010	<a href="#">Component/Part Identifier (CPID): AI (8010)</a>	N4+Y..30	(FNC1)	CPID
8011	<a href="#">Component/Part Identifier serial number: AI (8011)</a>	N4+N..12	(FNC1)	CPID SERIAL
8012	<a href="#">Software version: AI (8012)</a>	N4+X..20	(FNC1)	VERSION
8013	<a href="#">Global Model Number (GMN): AI (8013)</a>	N4+X..25	(FNC1)	GMN
8014 <sup>(8)</sup>	<a href="#">Highly Individualised Device Registration Identifier (HIDRI): AI (8014)</a>	N4+X..25	(FNC1)	MUDI
8017	<a href="#">Global Service Relation Number (GSRN) to identify the relationship between an organisation offering services and the provider of services: AI (8017)</a>	N4+N18	(FNC1)	GSRN - PROVIDER

137  
138  
139

NOTES:

(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:

- 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.7.11-3** 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.7.11-3** for GS1 AI encodable character set 64 (file-safe / URI-safe base64)
- [ ] enclosed value is an optional component

(2): If only year and month are available, DD must be filled with two zeroes, except where noted.

(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:

- 3100 Net weight in kg without a decimal point
- 3102 Net weight in kg with two decimal places  
see section **Error! Reference source not found.7.8.7** for further information.

- (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.
- (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.
- (6) The fourth digit of this GS1 Application Identifier indicates the sequence number, allowing for multiple occurrences of the AI.
- (7) The temperatures in these GS1 Application Identifiers are expressed in hundredths of degrees.
- (8) Restricted Global Model Number use as an attribute of GTIN SOLELY to register highly individualised medical devices in EUDAMED.

140  
141  
142  
143  
144  
145  
146  
147  
148  
149  
150  
151  
152  
153  
154  
155  
156  
157  
158  
159  
160  
161  
162  
163  
164

### 3.3 GS1 Application Identifiers starting with digit 0

#### 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 6.17 for the rules for GTIN formats and mandatory or optional attributes in the various trade item applications.

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)												Check digit	
		GS1-8 Prefix or GS1 Company Prefix						Item reference							
(GTIN-8)	0 3	0	0	0	0	0	0	N <sub>1</sub>	N <sub>2</sub>	N <sub>3</sub>	N <sub>4</sub>	N <sub>5</sub>	N <sub>6</sub>	N <sub>7</sub>	N <sub>8</sub>
(GTIN-12)	0 3	0	0	N <sub>1</sub>	N <sub>2</sub>	N <sub>3</sub>	N <sub>4</sub>	N <sub>5</sub>	N <sub>6</sub>	N <sub>7</sub>	N <sub>8</sub>	N <sub>9</sub>	N <sub>10</sub>	N <sub>11</sub>	N <sub>12</sub>
(GTIN-13)	0 3	0	N <sub>1</sub>	N <sub>2</sub>	N <sub>3</sub>	N <sub>4</sub>	N <sub>5</sub>	N <sub>6</sub>	N <sub>7</sub>	N <sub>8</sub>	N <sub>9</sub>	N <sub>10</sub>	N <sub>11</sub>	N <sub>12</sub>	N <sub>13</sub>
(GTIN-14)	0 3	N <sub>1</sub>	N <sub>2</sub>	N <sub>3</sub>	N <sub>4</sub>	N <sub>5</sub>	N <sub>6</sub>	N <sub>7</sub>	N <sub>8</sub>	N <sub>9</sub>	N <sub>10</sub>	N <sub>11</sub>	N <sub>12</sub>	N <sub>13</sub>	N <sub>14</sub>

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**

### 3.8 GS1 Application Identifiers starting with digit 8

#### 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), it is used for the unique identification of a family of standard contact lenses that will be registered in EUDAMED (European database on medical devices).

The structure and content of the grouping reference is at the discretion of the brand owner. It may contain all characters listed in figure **Error! Reference source not found.-1**.

The check character pair is explained in section **Error! Reference source not found.** 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 alpha character within the "grouping reference" data structure to ensure against any potential conflict with existing GTINs.

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

GS1 Application Identifier	Highly Individualised Device Registration Identifier (HIDRI)		
	GS1 Company Prefix	Grouping reference	Check characters
8 0 1 4	N <sub>1</sub> ... N <sub>i</sub>	X <sub>i+1</sub> ... variable length X <sub>j (j&lt;=23)</sub>	X <sub>j+1</sub> X <sub>j+2</sub>

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 **Error! Reference source not found.**) 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.

**Note:** This element string can be up to 25 characters in length and can go as low as 8 to 15 characters including the check character pair.

### 4.13.1 Invalid pairs of element strings

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

Some explanation on figure 4.13.1-1:

- The table is sorted by AI value, with the lowest AI value displayed in the first column.
- Multiple AIs may be listed in the first or third column, separated by commas. This means that the same rule applies to all listed AIs.
- The rules work in both directions, e.g., if it states AI (01) SHALL NOT be combined with AI (37) this implies that AI (37) SHALL NOT be combined with AI (01).

**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.




Invalid pairs of element strings				Rule
AI	Designation	AI	Designation	
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	<u>Identification of a made to order (MtO) trade item (GTIN)</u>	01 XOR 02	<u>GTIN or GTIN of contained trade items</u>	<u>Only one GTIN SHALL be used. Identification of a made to order (MtO) trade item (GTIN) SHALL NOT be used with any other GTIN</u>
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.

198

199 **4.13.2 Mandatory association of element strings**

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

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

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

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

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

223

224

**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 <sub>1</sub> = 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"> <li>variable count of items; or</li> <li>a trade measure</li> </ul> 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.
01 with N <sub>1</sub> = 9, 02 with N <sub>1</sub> = 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"> <li>variable count of items; or</li> <li>a trade measure; or</li> <li>the dimensions of a roll product.</li> </ul> Note: The first position of the GTIN is "9" for such trade items. Also see the note below this table.
01 with N <sub>1</sub> = 9 <u>or 03</u>	GTIN of a custom trade item <u>per Section 2.6.8 or made-to-order GTIN (03) per Section 2.6.17.</u>	242	The GTIN of a custom trade item <u>using AI (01)</u> 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. <u>The Made-to-Order variation number MAY also be used with Made-to-Order GTIN using AI (03).</u>
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 <u>XOR 03</u> ***	Batch/lot number SHALL occur in combination with: <ul style="list-style-type: none"> <li>a GTIN; or</li> <li>a GTIN of contained trade items; or</li> <li><u>Identification of a made to order (MtO) trade item (GTIN); or</u></li> <li>an ITIP</li> <li>an ITIP of contained trade item pieces</li> </ul>
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"> <li>a GTIN; or</li> <li>a GTIN of contained trade items; or</li> <li>an ITIP</li> <li>an ITIP of contained trade item pieces</li> </ul>
21	Serial number	01 XOR <u>03 XOR</u> 8006***	The serial number SHALL occur in combination with: <ul style="list-style-type: none"> <li>a GTIN; or</li> <li><u>Identification of a made to order (MtO) trade item (GTIN);-or</u></li> <li>an ITIP</li> </ul> Note: SGTIN is a common term for the combination of GTIN and serial number.
<u>8014</u>	<u>Highly Individualised Device Registration Identifier (HIDRI)</u>	<u>01</u>	<u>Highly Individualised Device Registration Identifier SHALL occur in combination with:</u> <ul style="list-style-type: none"> <li><u>a GTIN with AI (01)</u></li> </ul>

225  
226  
227

## 9 GS1 Standards glossary of terms

228  
229  
230  
231

### 9.1 GS1 glossary of terms and definitions

The glossary lists the terms and definitions that are applied in this document. Please refer to the [www.gs1.org/glossary](http://www.gs1.org/glossary) for the online version.

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).
<u>compound key</u>	<u>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).</u>
<u>Master Unique Device Identifier – Device Identifier (MUDI-DI)</u>	<u>The Master UDI-DI is a unique identifier specific to a family of highly individualised medical devices for the restricted use of EUDAMED registration.</u>
<u>standard contact lenses (per EU MDR)</u>	<u>A type of highly individualised device registered in EUDAMED per European Medical Device Regulations (MDR).</u>
<u>EUDAMED</u>	<u>European database on medical devices (EUDAMED) <a href="https://ec.europa.eu/health/medical-devices-eudamed/overview_en">https://ec.europa.eu/health/medical-devices-eudamed/overview_en</a></u>
<u>Made to Order (MtO) Trade Item</u>	<u>Any customised, personalised, or configurable trade item (bespoke product or service) upon which there is a need to share information and that may be priced, or ordered, or invoiced at any point in any supply chain using a compound GTIN key (e.g., SGTIN, LGTIN, GTIN+MtO Variant).</u>
<u>Highly Individualised Device (per EU MDR)</u>	<u>Device subject to EUDAMED registration via MUDI-DI as UDI-DI.</u>
<u>Highly Individualised Device Registration Identifier (HIDRI)</u>	<u>A Unique Device Identifier used for a consolidated group of products to register made-to-order devices used within EUDAMED.</u>
<u>simple key</u>	<u>A single data element that serves as a key (also see compound key).</u>

232  
233

### 9.3 GS1 abbreviations

Abbreviation	Term
<u>MtO</u>	<u>Made to Order</u>
<u>HIDRI</u>	<u>Highly Individualised Device Registration Identifier</u>

235