

WR #	GSCN Name	Effective Date
WR-21-283	AIDC Application Standard Master UDI-DI for registration of certain type of devices within EUDAMED	Aug 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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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 <u>GS1 System Architecture document</u>.

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 \underline{Z} .

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

Release 24.0, Ratified, Jan 24

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Page 139 of 517

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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 madeto-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-toorder 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)

Rules

See section 4.13

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:

- 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 as the MUDI-DI is made per the discretion of the brand owner,

Release 24.0, Ratified, Jan 24

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Page 140 of 517



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

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 (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 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 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:

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

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.

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

Release 24.0, Ratified, Jan 24

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Page 141 of 517



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.

Healthcare primary packaging (non-retail trade items)	<u>2.1.5</u>	<u>6</u>
Healthcare secondary packaging (regulated healthcare retail consumer trade items)	<u>2.1.6</u>	<u>8 or 10</u>

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

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
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Application	See section	SST(s)
Fixed measure trade items scanned at retail POS using:	<u>2.1.3</u>	
GTIN-12 or GTIN-13	<u>2.1.3.1</u>	1
GTIN-12 carried by a UPC-E barcode	<u>2.1.3.2</u>	1
GTIN-8	<u>2.1.3.3</u>	1
Hardcover books and paperbacks scanned at retail POS using ISBN, GTIN-13, or GTIN-12	<u>2.1.3.4</u>	1
Serial publications scanned at retail POS using ISSN, GTIN-13, or GTIN-12	<u>2.1.3.5</u>	1
Fixed measure fresh food trade items scanned at retail POS	<u>2.1.3.6</u>	1
Fixed measure trade items scanned in general distribution and at retail POS	<u>2.1.4</u>	3
Healthcare primary packaging (non-retail trade items)	<u>2.1.5</u>	6
Healthcare secondary packaging (regulated healthcare retail consumer trade items)	2.1.6	8 or 10
Fixed measure trade items scanned in general distribution	<u>2.1.7</u>	2

Release 24.0, Ratified, Jan 24

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3 GS1 Application Identifier definitions

3.1 Introduction

This section describes the meaning, structure and function of the GS1 system element strings so they can be correctly processed in users' application programmes. An element string is the combination of a GS1 Application Identifier and a GS1 Application Identifier data field. The allowable character set to be used for GS1 Application Identifier element strings is defined in section 7.11. There are AIs that have additional syntax restrictions, e.g., numerical only; see below definition for each AI.

Automatic processing of element strings in business applications requires information about the type of transaction to which the transferred data refers. See section Z for an explanation of this process. Element strings can be carried by GS1-128, GS1 DataBar symbology, GS1 Composite, GS1 DataMatrix and GS1 QR Code symbols. The rules for use and interrelationships between the GS1 Application Identifiers are contained in section 2 and 4.

When a predefined length GS1 key and attributes are encoded together, the GS1 key SHOULD appear before the attributes. In most cases predefined length element strings SHOULD be followed by non-predefined element strings. The sequence of predefined and non-predefined element strings should be at the discretion of the creator of the element strings.

3.2 GS1 Application Identifiers in numerical order

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	
<u>03</u>	Identification of a Made-to-Order (MtO) trade item (GTIN): AI (03)	<u>N2+N14</u>		MTO GTIN	Commented [DM8]: WR21-283
10	Batch or lot number: AI (10)	N2+X20	(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+X20	(FNC1)	SERIAL	
22	Consumer product variant: AI (22)	N2+X20	(FNC1)	CPV	
235	Third Party Controlled, Serialised Extension of Global Trade Item Number (GTIN) (TPX): AI (235)	N3+X28	(FNC1)	ТРХ	
240	Additional product identification assigned by the manufacturer: AI (240)	N3+X30	(FNC1)	ADDITIONAL ID	
241	Customer part number: AI (241)	N3+X30	(FNC1)	CUST. PART No.	
242	Made-to-Order variation number: AI (242)	N3+N6	(FNC1)	MTO VARIANT	
243	Packaging component number: AI (243)	N3+X20	(FNC1)	PCN	
250	Secondary serial number: AI (250)	N3+X30	(FNC1)	SECONDARY SERIAL	
251	Reference to source entity: AI (251)	N3+X30	(FNC1)	REF. TO SOURCE	

Release 25.025.024.0, DraftDraftRatified, Jan 25Jan 25Jan 24© 2024 GS1 AISBL

Page 147 of 526



AI	Data Content	Format ⁽¹⁾	FNC1 required ⁽⁴⁾	Data title
712	National Healthcare Reimbursement Number (NHRN) – Spain CN: AI (712)	N3+X20	(FNC1)	NHRN CN
713	National Healthcare Reimbursement Number (NHRN) – Brasil DRN: AI (713)	N3+X20	(FNC1)	NHRN DRN
714	National Healthcare Reimbursement Number (NHRN) – Portugal AIM: AI (714)	N3+X20	(FNC1)	NHRN AIM
715	National Healthcare Reimbursement Number (NHRN) – United States of America NDC: AI (715)	N3+X20	(FNC1)	NHRN NDC
716	National Healthcare Reimbursement Number (NHRN) – Italy AIFA: AI (716)	<u>N3+X20</u>	<u>(FNC1)</u>	NHRN AIFA
⁽⁵⁾	National Healthcare Reimbursement Number (NHRN) – Country "A" NHRN	N3+X20	(FNC1)	NHRN xxx
723s (6)	Certification reference: AI (723s)	N4+X2+X28	(FNC1)	CERT # s
7240	Protocol ID: AI (7240)	N4+X20	(FNC1)	PROTOCOL
7241	AIDC media type: AI (7241)	N4+N2	(FNC1)	AIDC MEDIA TYPE
7242	Version Control Number (VCN): AI (7242)	N4+X25	(FNC1)	VCN
7250	Date of birth: AI (7250)	<u>N4+N8</u>	(FNC1)	DOB
7251	Date and time of birth: AI (7251)	<u>N4+N12</u>	(FNC1)	DOB TIME
7252	Biological sex: AI (7252)	<u>N4+N1</u>	<u>(FNC1)</u>	BIO SEX
7253	Family name of person: AI (7253)	<u>N4+X40</u>	<u>(FNC1)</u>	FAMILY NAME
7254	Given name of person: AI (7254)	<u>N4+X40</u>	(FNC1)	GIVEN NAME
7255	Name suffix of person: AI (7255)	<u>N4+X10</u>	<u>(FNC1)</u>	<u>SUFFIX</u>
7256	Full name of person: AI (7256)	<u>N4+X90</u>	<u>(FNC1)</u>	FULL NAME
7257	Address of person: AI (7257)	<u>N4+X70</u>	<u>(FNC1)</u>	PERSON ADDR
7258	Baby birth sequence indicator: AI (7258)	$N4+N_1+X_1+N_1$	(FNC1)	BIRTH SEQUENCE
7259	Baby of family name: AI (7259)	<u>N4+X40</u>	<u>(FNC1)</u>	BABY
8001	Roll products - width, length, core diameter, direction, splices: AI (8001)	N4+N14	(FNC1)	DIMENSIONS
8002	Cellular mobile telephone identifier: AI (8002)	N4+X20	(FNC1)	CMT No.
8003	Global Returnable Asset Identifier (GRAI): AI (8003)	N4+N14[+X16]	(FNC1)	GRAI
8004	<u>Global Individual Asset Identifier (GIAI): AI</u> (8004)	N4+X30	(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+X34	(FNC1)	IBAN
8008	Date and time of production: AI (8008)	N4+N8[+N4]	(FNC1)	PROD TIME
8009	Optically readable sensor indicator: AI (8009)	N4+X50	(FNC1)	OPTSEN
8010	Component/Part Identifier (CPID): AI (8010)	N4+Y30	(FNC1)	CPID
8011	Component/Part Identifier serial number: AI (8011)	N4+N12	(FNC1)	CPID SERIAL
8012	Software version: AI (8012)	N4+X20	(FNC1)	VERSION
8013	Global Model Number (GMN): AI (8013)	N4+X25	(FNC1)	GMN
<u>8014</u>	Highly Individualised Device Registration Identifier (HIDRI): AI (8014)	<u>N4+X25</u>	<u>(FNC1)</u>	MUDI

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Release 25.025.024.0, DraftDraftRatified, Jan 25Jan 25Jan 24© 2024 GS1 AISBL

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Page 152 of 526



AI	Data Content	Format ⁽¹⁾	FNC1 required ⁽⁴⁾	Data title
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
8018	Global Service Relation Number (GSRN) to identify the relationship between an organisation offering services and the recipient of services: AI (8018)	N4+N18	(FNC1)	GSRN - RECIPIENT
8019	Service Relation Instance Number (SRIN): AI (8019)	N4+N10	(FNC1)	SRIN
8020	Payment slip reference number: AI (8020)	N4+X25	(FNC1)	REF No.
8026	Identification of pieces of a trade item (ITIP) contained in a logistic unit: AI (8026)	N4+N14+N2+N2	(FNC1)	ITIP CONTENT
8030	Digital Signature (DigSig): AI (8030)	N4+Z90	(FNC1)	DIGSIG
8110	Coupon code identification for use in North America (AI 8110)	N4+X70	(FNC1)	-
8111	Loyalty points of a coupon: AI (8111)	N4+N4	(FNC1)	POINTS
8112	Positive offer file coupon code identification for use in North America: (AI 8112)	N4+X70	(FNC1)	-
8200	Extended packaging URL: AI (8200)	N4+X70	(FNC1)	PRODUCT URL
90	Information mutually agreed between trading partners: AI (90)	N2+X30	(FNC1)	INTERNAL
91 to 99	Company internal information: AIs (91 - 99)	N2+X90	(FNC1)	INTERNAL

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 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 numerica 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 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 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 <u>7.8.5-2</u> 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 <u>7.8.4</u>.



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: $\ensuremath{\textbf{GTIN}}$

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 $\underline{2}$ 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.

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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 o	of the	element	string
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	GS1					Gl	obal ⁻	Гrade	Item	Num	nber (GTIN)		
	Application Identifier	GS1	GS1-8 Prefix or GS1 Company Prefix							Item reference			Check digit		
(GTIN-8)	02	0	0	0	0	0	0	N_1	N_2	N_3	N_4	N_5	N_6	N ₇	N ₈
(GTIN-12)	02	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)	02	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)	02	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 2.6.176.17 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 3.3.4-3-1 Format of the element string														
			Identification of a Made-to-Order (MtO) trade item (GTIN)												
		<u>GS1</u>												ence	<u>Check</u> <u>digit</u>
<u>(GTIN-8)</u>	<u>0 3</u>	0	0	0	0	0	0	<u>N1</u>	<u>N2</u>	<u>N3</u>	<u>N4</u>	<u>N5</u>	<u>N₆</u>	N _Z	<u>N</u> 8
<u>(GTIN-12)</u>	<u>0 3</u>	0	0	N_1	N ₂	N ₃	N ₄	N ₅	N ₆	N ₇	N ₈	N ₉	N ₁₀	N ₁₁	<u>N₁₂</u>
<u>(GTIN-13)</u>	<u>0 3</u>	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	<u>N₁₃</u>
<u>(GTIN-14)</u>	<u>03</u>	<u>N</u> 1_	<u>N2</u>	<u>N</u> 3	<u>N4</u>	<u>N5</u>	<u>N₆</u>	N _Z	<u>N</u> 8	<u>N9</u>	N ₁₀	N ₁₁	N ₁₂	N ₁₃	<u>N₁₄</u>

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**

3.4 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 manufacturer are responsible for ensuring the non-duplication of batch/lot numbers or 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	$X_1 \longrightarrow variable length \longrightarrow X_{20}$

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.



Ap

eck

characters

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.

	Figure 3.9.13-1	. Format of the element string	
GS1		Global Model Number (GMN)	
Application Identifier	GS1 Company Prefix	Model reference	Cł

8013 N1 ... Ni variable length $X_{j+1}\ X_{j+2}$ X_{i+1} ... X_{j (j<=23)} 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 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 figure 7.11-1.

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.

Figure 3.8.22-1 Format of the element string

<u>GS1</u>				sed Device Registration Identifier (HIDRI)		
Application	<u>GS1 Com</u>	<u>pany Prefi</u>		Grouping reference		Check
<u>100111</u>		N		variable length	<u>````````````````````````````````</u>	<u>cnaracters</u>
8014	<u>N1</u>	<u>IN</u> i	<u>Xi+1</u>	<u>variable length</u>	<u>Xj (j<=23)</u>	$\underline{\lambda_{j+1}}$ $\underline{\lambda_{j+2}}$

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 1.4.4) 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

Release 24.0, Ratified, Jan 24

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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 item reference, and the check character pair.

3.9.143.9.15 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 1.4.4). 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.

Figure 3.9.14-1. Format of the element string

GS1	GS1 Global Service Relation Number (GSRN) - PROVIDER	
Application Identifier	GS1 Company Prefix Service reference	Check
		uigit
8017	N1 N2 N3 N4 N5 N6 N7 N8 N9 N10 N11 N12 N13 N14 N15 N16 N17	N18

The data transmitted from the barcode reader means that the element string denoting the Global Service Relation Number for the Provider 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: **GSRN – PROVIDER**

The Global Service Relation Number – Recipient identifies the relationship between an organisation offering services and the recipient of services.

Figure 3.9.14-2. Format of the element string

GS1	GS1 Global Service Relation Number (GSRN) - RECIPIENT	
Application Identifier	GS1 Company Prefix Service reference	Check
		uigit
8018	$N_1 \ N_2 \ N_3 \ N_4 \ N_5 \ N_6 \ N_7 \ N_8 \ N_9 \ N_{10} \ N_{11} \ N_{12} \ N_{13} \ N_{14} \ N_{15} \ N_{16} \ N_{17}$	N ₁₈

The data transmitted from the barcode reader means that the element string denoting Global Service Relation Number for the Recipient 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: **GSRN** - **RECIPIENT**



Note: AI (8017) and AI (8018) must not be used in combination, see section <u>4.13</u> Data relationships.

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4.13 Data relationships

This section defines the rules for allowed combinations of element strings on the same physical entity, irrespective of the data carrier(s) applied to the entity. The rules are application-neutral, which means that they apply to all applications listed in section 2 and to any other application where multiple element strings are combined on the same physical entity.

The rules are presented in two tables:

- 1. Invalid pairs of element strings, indicating which combinations of element strings are not allowed on the same physical entity.
- 2. Mandatory pairs of element strings, indicating which element strings must occur in combination with one or more other element strings.



Note: In both tables, the GS1 Application Identifiers (AIs) are used to indicate the element string. But when evaluating the rule the complete element string, i.e. the AI and the data field, needs to be taken into account.



Note: GTINs encoded in an EAN/UPC and ITF-14 symbols are to be regarded as element strings prefixed by an inferred AI (01).



Note: Duplicate element strings (e.g., two serial numbers, two batch/lot numbers, two Extended Packaging URLs) MAY appear on the same physical entity (for example in multiple barcodes). In that case they SHALL have the same value in each occurrence on that entity.

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).
- For the purpose of this table Made-to-Stock (MtS) GTIN AI (01) and Made-to-Order (MtO GTIN AI (03) are simply referred to as GTIN.

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.
<u>01</u>	GTIN	<u>03</u>	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 <u>, 03</u>	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.

Figure 4.13.1-1. Invalid pairs of element strings



Invalid pairs of element strings				Rule
AI	Designation	AI	Designation	
01	GTIN	255	Global Coupon Number	A trade item SHALL NOT also be identified as a coupon.
<u>03</u>	GTIN	<u>02</u>	<u>GTIN of contained</u> 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.
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.
420	Ship to postal code, single postal authority	421	Ship to postal code with ISO country code	Only one ship to postal code SHALL be applied on the same physical entity.
421	Ship-to / Deliver- to postal code with three-digit ISO country code	4307	Ship-to / Deliver- to country code	Only one ship to country code SHALL be applied on the same physical entity.
422, 423, 424, 425	Country of origin, initial processing, processing, or disassembly	426	Country of full processing	Country of origin, initial processing, processing, or disassembly SHALL NOT be used in combination with country of full processing, since this would lead to ambiguous data.
390n	Amount payable – single monetary area	391n	Amount payable – with ISO currency code	Only one amount payable element string SHALL be applied on a payment slip.
390n	Coupon value	394n, 8111	Percentage discount of a coupon, Loyalty points of a coupon	The element strings coupon value, percentage discount of a coupon and loyalty points of a coupon SHALL NOT be applied in combination.
392n	Amount payable for a variable measure trade item – single monetary area	393n, 395n	Amount payable for a variable measure trade item and ISO currency code, Amount payable per unit of measure single monetary area (variable measure trade item)	Only one amount payable element string SHALL be applied on a variable measure trade item.
394n	Percentage discount of a coupon	8111	Loyalty points of a coupon	The element strings percentage discount of a coupon and loyalty points of a coupon SHALL NOT be applied in combination.
395n	Amount payable per unit of measure single monetary area (variable measure trade item)	8005	Price per unit of measure	The element strings Amount payable per unit of measure single monetary area (variable measure trade item) and Price per unit of measure SHALL NOT be applied in combination.
395n	Amount payable per unit of measure single monetary area (variable measure trade item)	392n, 393n	Applicable amount payable, single monetary area (variable measure trade item), Applicable amount payable with ISO currency code (variable measure trade item)	Only one amount payable element string SHALL be applied on a variable measure trade item.

Release 24.0, Ratified, Jan 24



Invalid pairs of element strings				Rule
AI	Designation	AI	Designation	
4330	Maximum temperature in Fahrenheit	4331	Maximum temperature in Celsius	Only a single maximum temperature SHALL be used in combination with an SSCC
4332	Minimum temperature in Fahrenheit	4333	Minimum temperature in Celsius	Only a single minimum temperature SHALL be used in combination with an SSCC
8006	ITIP	01	GTIN	The GTIN SHALL NOT be used in combination with the identification of an individual trade item piece. The GTIN of the trade item to which the individual trade item piece belongs is contained in the element string.
8006	ITIP	37	Count of units contained	The count of units contained SHALL only be used with GTIN of contained trade items or trade item pieces.
8018	GSRN for the recipient	8017	GSRN for the provider	Only one Global Service Relation Number (recipient or provider) SHALL be applied at one time for identification of an individual in a given service relationship
8026	Identification of a trade item piece contained in a logistic unit	02, 8006	GTIN of contained trade items, Identification of an individual trade item piece	Identification of the trade item piece contained in a logistic unit SHALL NOT be used in combination with GTIN of contained trade items or identification of an individual trade item piece.

4.13.2 Mandatory association of element strings

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

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

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

Some explanation on figure 4.13.2-1:

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

Release 24.0, Ratified, Jan 24

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Page 237 of 517



If element string		Then mandatory associated element string	Rule
AI	Designation	AI	
$01 \text{ with } N_1 = 0$	GTIN of a variable measure trade	30 OR 3nnn*	The GTIN of a variable measure trade item scanned at POS SHALL occur in combination with:
	POS		 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.
01 with N ₁ = 9, 02	GTIN of a variable measure trade	30 OR 3nnn* OR 8001	The GTIN of a variable measure trade item not scanned at POS SHALL occur in combination with:
with $N_1 =$	item not scanned		 variable count of items; or
9	al PUS		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 N1 = 9 <u>or</u> 03	GTIN of a custom trade item.Made to Order Variation	242GTIN of a custom trade item per section	The GTIN of a custom trade item <u>using AI (01) and indicator digit</u> <u>"9"</u> SHALL be used in combination with the Made-to-Order variation number.
	Number AI (242)	2.6.8 or Made- to-Order GTIN (03)	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: a GTIN; or a GTIN of contained trade items; or <u>Identification of a Made-to-Order (MtO) trade item (GTIN): or</u> a n ITIP <u>; or</u> a n 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: • a GTIN; or • a GTIN of contained trade items; or • an ITIP • an ITIP of contained trade item pieces
12	Due date	8020 AND 415	The due date SHALL occur in combination with the payment slip reference number and the GLN of the invoicing party
17	Expiration date (of a coupon)	255	The expiration date of a coupon SHALL occur in combination with the GCN.
20	Internal product variant	01 XOR 02 XOR 8006 XOR 8026 ***	Internal product variant SHALL occur in combination with: • a GTIN; or • a GTIN of contained trade items; or • an ITIP • an ITIP of contained trade item pieces
21	Serial number	01 XOR <u>03 XOR</u> 8006***	The serial number SHALL occur in combination with: • a GTIN; or • <u>Identification of a Made-to-Order (MtO) trade item (GTIN); or</u> • an ITIP Note: SGTIN is a common term for the combination of GTIN and serial number.
22	Consumer product variant	01	The consumer product variant SHALL occur in combination with a GTIN of a retail consumer trade item.

Figure 4.13.2-1. Mandatory association of element strings

Release 24.0, Ratified, Jan 24

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Page 238 of 517



If element string		Then mandatory associated element string	Rule	
AI	Designation	AI		
8005	Price per unit of measure	01 XOR 02	The price per unit of measure SHALL occur in combination with: a GTIN; or a GTIN of contained trade items. Note: The GTIN must relate to a variable measure trade item.	
8007	International Bank Account Number	8020 AND 415	The International Bank Account Number SHALL occur in combination with the payment slip reference number and the GLN of the invoicing party.	
8008	Date and time of production	01 XOR 02	The date and time of production SHALL occur in combination with: a GTIN; or a GTIN of contained trade items.	
8009	Optically readable sensor indicator	01 OR 00	The Optically Readable Sensor Indicator Number SHALL occur in combination with the GTIN or SSCC. Note the two data elements may or may not appear in the same data carrier.	
8011	CPID serial number	8010	The CPID serial number SHALL occur in combination with the CPID.	
8012	Software Version	01 XOR 8006***	The software version SHALL occur in combination with: a GTIN; or an ITIP	
8014	Highly Individualised Device Registration Identifier (HIDRI)	<u>01</u>	Highly Individualised Device Registration Identifier SHALL occur in combination with: a GTIN with AI (01)	
8019	Service Relation Instance Number	8017 XOR 8018	The Service Relation Instance Number SHALL occur in combination with: the GSRN for the provider; or the GSRN for the recipient.	
8020	Payment slip reference number	415	The payment slip reference number SHALL occur in combination with the GLN of the invoicing party.	
8026	ITIP of contained pieces	00 AND 37	The ITIP of contained pieces SHALL occur in combination with an SSCC and the count of the pieces.	
8030	Digital Signature (DigSig)	(01 AND 21) XOR (8006 AND 21) XOR (8010 AND 8011) XOR 8003 XOR 8004 XOR 8017 XOR 8017 XOR 8018 XOR 00 XOR 253 XOR 255	 The Digital Signature (DigSig) SHALL occur in combination with one of the following: Global Trade Item Number and Serial number Identification of an individual trade item piece and Serial number Component/Part Identifier and Component/Part Identifier serial number Global Returnable Asset Identifier including Serial component Global Individual Asset Identifier Global Service Relation Number - Provider Global Scrvice Relation Number - Recipient Serial Shipping Container Code Global Document Type Identifier including Serial component Global Coupon Number including Serial component 	
8111	Loyalty points of a coupons	255	Loyalty points of a coupon SHALL occur in combination with the GCN.	
8200	Extended packaging URL	01	The extended packaging URL SHALL occur in combination with the GTIN.	
* The No:	The AIs for trade measures are set out in section <u>3.6.2</u> <i>Trade measures: AIs (31nn, 32nn, 35nn, 36nn).</i> Note: All AIs in section <u>3.6.2</u> can be used with this AI 395n.			

Release 24.0, Ratified, Jan 24

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Page 243 of 517



9 GS1 Standards glossary of terms

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 $\underline{www.gs1.org/glossary}$ for the online version.

Territ	Definition
acceptance criteria	An allowance for a small measurement variation between commercial verifiers or operators during barcode verification testing.
add-on symbol	A barcode used to encode information supplementary to that in the main EAN/UPC barcode.
aggregated packaging (per EU 2018/574)	Any packaging containing more than one unit packet of tobacco products. For GS1, this may be either a trade item grouping or logistics unit.
AIDC media	The specific form of object/entity where a GS1 AIDC data carrier is displayed.
AIDC media type	The code list for objects/entities (e.g., patient wristband or staff ID card) that displays or carries a GS1 AIDC data carrier.
AIDC media type value	A predefined two-digit numeric code list value used to signify the AIDC media type (e.g., $ID = 10$, patient wristband = 01).
AIM DotCode	A two-dimensional barcode symbology rendered by printing dots per the AIM DotCode Specification.
allocation	The association of an issued GS1 Prefix, GS1 Company Prefix, or GS1 identification key to its corresponding entity or object in accordance with the GS1 rules and policies.
alphanumeric	A character set that contains alphabetic characters (letters), numeric digits (numbers) and other characters, such as punctuation marks.
aperture	A physical opening that is part of the optical path in a device such as a scanner, photometer, or camera. Most apertures are circular, but they may be rectangular or elliptical.
Application Standard Profile	A template that records conformance requirements of existing and any future AIDC application standards, the normative decisions (MSWG, ISO, Regulation,), maintains centralisation of cross-application rules and related technical specifications.
asset type	A component of the Global Returnable Asset Identifier (GRAI), assigned by the asset owner or manager, in order to create a unique GRAI.
attribute	Additional information about an entity identified with a GS1 identification key.
autodiscrimination	The capability of a reader to automatically recognise and decode multiple barcode symbologies.
automatic identification and data capture (AIDC)	A technology used to automatically capture data. AIDC technologies include barcodes, smart cards, biometrics and RFID.
auxiliary patterns	Components of the EAN/UPC symbology. The centre guard bar pattern, the left guard bar pattern and the right guard bar pattern are examples of these.
bar gain/loss	The increase/decrease in bar width due to effects of the reproduction and printing processes.
barcode	A symbol that encodes data into a machine readable pattern of adjacent, varying width, parallel, rectangular or square dark and light spaces. The term barcode is inclusive of all linear and two-dimensional (2D) versions.
barcode verification	The assessment of the printed quality of a barcode based on ISO/IEC standards using ISO/IEC compliant barcode verifiers.
base unit	In a hierarchy of trade item groupings, the consumer trade item level or unit of use.
Basic Unique Device Identifier – Device Identifier (<u>Basic</u> UDI-DI)	The Basic UDI - DI is a unique identifier specific to a medical device product family. It is represented by GS1's Global Model Number (GMN).
batch/lot	Associates an item with information the manufacturer considers relevant for traceability of the trade item.
bearer bars	Bar abutting the tops and bottoms of the bars in a barcode or a frame surrounding the entire symbol, intended to equalise the pressure exerted by the printing plate over the entire surface of the symbol and/or to prevent a partial scan by the barcode reader.
brand owner	The organisation that owns the specifications of a trade item, regardless of where and by whom it is manufactured. The brand owner is normally responsible for the management of the Global Trade Item Number (GTIN).

Release 24.0, Ratified, Jan 24

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Term	Definition
Character Set 39	A subset of characters found in ISO 646: Unique Graphic Character Allocations which includes
	numeric, alphabetic upper-case, plus the characters "#", "-" and "/".
Character Set 64 (file- safe / URI-safe base64)	A subset of characters found in ISO 646: Unique Graphic Character Allocations and defined by section 5 of RFC4648 as a URI and filename safe base64 alphabet, which includes numeric, alphabetic upper-case and lower-case, plus the characters "-", "_". The "=" character is used as a special pad character and has no assigned value. The file-safe URI-safe base64 alphabet is used to represent binary data as compact alphanumeric strings, each character corresponding to a 6-bit value in the range 0-63.
Character Set 82	A subset of characters found in ISO 646: Unique Graphic Character Allocations which includes numeric, alphabetic upper-case and lower-case, plus twenty special characters but excluding "space".
check character pair	A final character pair calculated from the other characters of the Global Model Number. These characters are used to check that the data has been correctly composed and transmitted.
check digit	Numeric character calculated from data and appended as part of the data string to ensure that the data is correctly composed and transmitted.
codeword	A symbol character value. An intermediate level of coding between source data and the graphical encodation in the symbol.
component/part	An item that is intended to undergo at least one further transformation process to create finished goods for the purpose of downstream consumption.
Component/Part Identifier (CPID)	The unique identifier for a component/part, comprising a GS1 Company Prefix and a component/part reference.
Composite Component	The stacked linear barcode component of a GS1 composite symbol.
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).
concatenation	The representation of several element strings in one barcode.
Conformant	The state in which a system meets a specified standard.
consignment	A grouping of logistic or transport units assembled by a freight forwarder or carrier to be transported under one transport document (e.g., waybill).
consumer product variant (CPV)	An alphanumeric attribute of a GTIN assigned to a retail consumer trade item variant for its lifetime.
country subdivision	Principle administrative divisions, or similar areas, of a country included in <i>ISO 3166-1</i> . Examples are a state in the US, a region in France, a canton in Swiss.
coupon	A voucher that can be redeemed at the point-of-sale for a cash value or free item.
coupon issuer	Party issuing the coupons, bearing the commercial and financial responsibility for the coupons.
customer	The party that receives, buys, or consumes an item or service.
data character	A single numeric digit, alphabetic character or punctuation mark, or control character, which represents meaningful information.
data field	A field that contains a GS1 identification key, an RCN, or attribute information.
Data Matrix (GS1 Digital Link URI)	Data Matrix encoding data using the uncompressed form of GS1 Digital Link URI syntax.
Data Matrix symbology	A standalone, two-dimensional barcode symbology that is made up of square modules arranged within a perimeter finder pattern. Data Matrix using ECC 200 error correction is the only version that supports GS1 system identification keys, including the Function 1 Symbol Character (FNC1). Data Matrix symbols are read by two-dimensional imaging scanners or vision systems.
data titles	Data titles are the abbreviated descriptions of element strings which are used to support manual interpretation of barcodes.
digital coupon	A digital coupon is an electronic presentation, that is distributed and presented without manifesting as "paper" or in other hard-copy form, and that can be exchanged for a financial saving or for loyalty points when making a purchase.
Digital Signature (DigSig)	ISO/IEC 20248 defines a data construct for encoding a digital signature within a data carrier, providing a method to authenticate barcode and RFID data. It also provides a method to link the barcode and RFID data to the labelled/tagged object. The ISO/IEC 20248 data construct which contains a X.509 digital signature is known as a DigSig. "digital signature" in lower case refers to digital signatures in general, whilst "Digital Signature" with capitals, is a named thing with the specific meaning of "DigSig".

Release 24.0, Ratified, Jan 24

© 2024 GS1 AISBL

Page 506 of 517



Term	Definition
digital signature	A digital signature is a compact fingerprint of data that supports tamper-detection and non- repudiation by the party who digitally signed the data. A digital signature is constructed by hashing the data then encrypting the hash using the private key. This enables independent verification by anyone, using the public key.
direct mode	Mobile device information retrieval function when the barcode contains either the address (URL) of the content or service, or the content itself, in-line.
direct part marking (DPM)	Direct part marking refers to the process of marking a symbol on an item using an intrusive or non-intrusive method.
direct print	A process in which the printing apparatus prints the symbol by making physical contact with a substrate (e.g., flexography, ink jet, dot peening).
document type	A component of a Global Document Type Identifier (GDTI) assigned by the document issuer to create a unique GDTI.
dynamic assortment	A trade item that comprises a variable composition of a fixed total count of two or more different trade items, each identified with a GTIN.
EAN/UPC symbology	A family of barcodes including EAN-8, EAN-13, UPC-A and UPC-E barcodes as well as the 2- and 5-digit add-ons. See also EAN-8 barcode, EAN-13 barcode, UPC-A barcode and UPC-E barcode.
EAN-13 barcode	A barcode of the EAN/UPC symbology that encodes GTIN-13 or RCN-13.
EAN-8 barcode	A barcode of the EAN/UPC symbology that encodes GTIN-8 or RCN-8.
economic operator (per EU 2018/574)	An economic operator is a business or other organisation which supplies goods, works or services within the context of market operations. Related to requirement for EOID for each country in which a party operates a facility.
Electronic Product Code (EPC)	An identification scheme for universally identifying physical objects (e.g., trade items, assets and locations) via RFID tags and other means. The standardised EPC data consists of an EPC (or EPC Identifier) that uniquely identifies an individual object, as well as an optional filter value when judged to be necessary to enable effective and efficient reading of the EPC tags.
element	A single bar or space of a linear barcode symbol.
EU 2018/574	A European Union Regulation on the traceability of tobacco products.
EUDAMED	European database on medical devices (EUDAMED)
	https://ec.europa.eu/health/medical-devices-eudamed/overview_en
even parity	A characteristic of the encodation of a symbol character whereby the symbol character contains an even number of dark modules.
extended packaging	An approach to giving consumers access to additional information or services about trade items through their mobile device. It is the ability to retrieve additional information about the trade item through mobile devices or, in general, to link a trade item with trusted virtual information or services.
extension digit	The first digit within the Serial Shipping Container Code (SSCC) which is assigned by the company that constructs the logistic unit.
facility (per EU 2018/574)	Any location, building or vending machine where tobacco products are manufactured, stored or placed on the market.
fixed length	Term used to describe a data field in an element string with an established number of characters.
fixed measure trade item	An item always produced in the same predefined version (e.g., type, size, weight, contents, design) that may be sold at any point in the supply chain.
freight forwarder	The party that arranges the carriage of goods including connected services and/or associated formalities on behalf of the shipper (consignor) or consignee.
fresh foods	Trade items in the following product categories: fruits, vegetables, meats, seafood, bakery and ready to serve food such as cheeses, cold cooked or cured meats and salad, etc. Fresh foods are defined as food that is not preserved by canning, dehydration, freezing or smoking.
full string	The data transmitted by the barcode reader from reading a data carrier, including the symbology identifier as well as the encoded data.
Function 1 Symbol Character (FNC1)	A symbology character used in some GS1 data carriers for specific purposes.
general distribution scanning	Scanning environments that process barcoded trade items packaged for transport, logistic units, assets and location tags.

Release 24.0, Ratified, Jan 24

© 2024 GS1 AISBL

Page 507 of 517



Term	Definition
GS1 symbologies using GS1 Application Identifiers	All GS1 endorsed barcode symbologies that can encode more than a GTIN namely GS1-128, GS1 DataMatrix, GS1 DataBar, GS1 QR Code, GS1 DotCode and GS1Composite.
GS1 syntax	A data structure used within the GS1 system of standards for representing data elements. GS1 syntax includes plain syntax, GS1 element string, GS1 Digital Link URI, and Electronic Product Code (EPC) URI.
GS1 system	The specifications, standards and guidelines administered by GS1.
GS1 UIC Extension 1	Character that follows and extends the EU 2018/574 UIC to identify a country of ID Issuer's appointment and operation.
GS1 UIC Extension 2	Character that follows GS1 UIC Extension 1 and extends the EU 2018/574 UIC to identify whether a GS1 or non-GS1 based algorithm is used.
GS1 XML	The GS1 standard for extensible markup language (XML) schemas providing users with a global business messaging language of e-business to conduct efficient internet-based commerce.
GS1®	Based in Brussels, Belgium and Princeton, USA, it is the organisation that manages the GS1 system. Its members are GS1 Member Organisations.
GS1-128 symbology	A subset of Code 128 which uses the function that allows the encoding of element strings.
GS1-8 Prefix	A unique string of two or more digits issued by GS1 Global Office and allocated to GS1 Member Organisations to issue GTIN-8s or allocated to issue RCN-8s (see RCN-8).
GTIN allocator	The party that warrants the trade item declarations about a trade item to which they allocate a GTIN. This is the party who is the licensee of the GTIN applied to a specific trade item.
GTIN plus attribute(s) flag	A trigger in systems to determine if additional processing is required by a barcode user for a given GTIN.
GTIN-12	The 12-digit GS1 identification key composed of a U.P.C. Company Prefix, item reference and check digit used to identify trade items.
GTIN-13	The 13-digit GS1 identification key composed of a GS1 Company Prefix, item reference and check digit used to identify trade items.
GTIN-14	The 14-digit GS1 identification key composed of an indicator digit (1-9), GS1 Company Prefix, item reference and check digit used to identify trade items.
GTIN-8	The 8-digit GS1 identification key composed of a GS1-8 Prefix, item reference and check digit used to identify trade items.
guard bar pattern	An auxiliary pattern of bars and spaces corresponding to start or stop patterns in barcode symbologies, and serving to separate the two halves of EAN-8, EAN-13 and UPC-A symbols.
healthcare primary packaging	The first level of packaging for the product marked with an AIDC data carrier either on the packaging or on a label affixed to the packaging. For non-sterile packaging, the first level of packaging can be the packaging in direct contact with the product. For sterile packaging, the first level of packaging can be any combination of the sterile packaging system, May consist of a single item or group of items for a single therapy such as a kit. For packaging configurations that include a retail consumer trade item, primary packaging is a packaging level below the retail consumer trade item.
healthcare provider	An organisation or facility that delivers healthcare to a subject of care. Corresponds to "care delivery organisation", "healthcare organisation", etc.
healthcare secondary packaging	A level of packaging marked with an AIDC carrier that may contain one or more primary packages each of which may contain a single item or multiple items.
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.
House Waybill Number	A freight forwarder's document used mainly as a control for the goods within the freight forwarder's own service system.
human readable interpretation(HRI)	Characters, such as letters and numbers, which can be read by persons and are encoded in GS1 AIDC data carriers confined to a GS1 standard structure and format. The human readable interpretation is the encoded data. Start, stop, shift and function characters, as well as the symbol check character, are not shown in the human readable interpretation.
human readable text	Refers to HRI and/or non-HRI text collectively, when referencing data that is encoded into a data carrier.

Release 24.0, Ratified, Jan 24

© 2024 GS1 AISBL

Page 510 of 517



Term	Definition
Importer index (per EU 2018/574)	Character to identify the presence or absence of an importer within the EU 2018/574 EOID, FID and MID. This means either the absence of an importer (null) or presence of one importer out of up to 63 importer possibilities per country, per GTIN.
indicator	A digit from 1 to 9 in the leftmost position of the GTIN-14.
indirect mode	Mobile device information retrieval function when the code contains an identifier, which needs to be resolved to obtain the content or service. Resolving an identifier means looking it up, typically at a network service, to determine the corresponding content or service.
individual asset	An object that is part of the inventory of assets for a given company. (See also returnable asset.)
individual asset reference	A component of the Global Individual Asset Identifier (GIAI) assigned by the asset owner or manager to create a unique GIAI.
individual provider	Any person who provides or is a potential provider of a health care service to a subject of care.
Interleaved 2-of-5 symbology	Barcode symbology used for the ITF-14 barcode.
inverse exponent	The GS1 Application Identifier digit that denotes the implied decimal point position in an element string.
issuance	The generation of a GS1 Prefix, GS1 Company Prefix, or GS1 identification key in accordance with GS1 rules and policies by GS1 or a GS1 Member Organisation.
item reference	A component of the Global Trade Item Number (GTIN) assigned by the brand owner to create a unique GTIN.
ITF-14 barcode	ITF-14 (a subset of Interleaved 2-of-5) barcodes carry GTINs only on trade items that are not expected to pass through the point-of-sale.
kit	A collection of different regulated healthcare items assembled for use in a single therapy.
leading zero(es)	Adding zeroes in the leftmost position(s) of a data string when GTIN-8, GTIN-12, or GTIN-13 are encoded in an GS1 AIDC data carrier, message, or database that requires 14-digits or when used for the same intent in other data structures such as GRAI.
levels of AIDC marking	A graduated system of AIDC marking. The graduated system is defined as minimum, enhanced and highest levels of AIDC marking.
linear barcode	Barcode symbology using bars and spaces in one dimension.
local assigned code (LAC)	A particular use of the UPC-E barcode for restricted distribution.
location reference	A component of a Global Location Number (GLN) that allows the party defining the party or location to create a unique GLN.
logistic measures	Measures indicating the outside dimensions, total weight, or volume inclusive of packing material of a logistic unit. Also known as gross measures.
logistic unit	An item of any composition established for transport and/or storage that needs to be managed through the supply chain. It is identified with a Serial Shipping Container Code (SSCC).
<u>Made-to-Order (MtO)</u> <u>trade item</u>	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.
<u>Made-to-Stock (MtS)</u> <u>trade item</u>	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.
<u>Master Unique Device</u> <u>Identifier – Device</u> <u>Identifier (MUDI-DI)</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.
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.

Release 24.0, Ratified, Jan 24

© 2024 GS1 AISBL

Page 511 of 517



Term	Definition
service reference	A component of the Global Service Relation Number (GSRN) assigned by the issuing organisation to create a unique GSRN.
service relation instance number (SRIN)	An attribute to the GSRN which allows to distinguish different encounters during a service relationship.
shipment	A grouping of logistic and transport units assembled and identified by the seller (sender) of the goods travelling under one despatch advice and/or Bill of Lading to one customer (recipient).
short life items	An item, preparation or reconstituted product with limited use/shelf life.
simple key	A single data element that serves as a key (also see compound key).
single unit package/blister	A healthcare primary package that contains one discrete pharmaceutical dosage form, i.e. a tablet, a certain volume of a liquid or that is the immediate package for a medical device like a syringe. A number of single units attached to each other, but are easily separated through a perforation would be included.
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)
sterile packaging system	A combination of the sterile barrier system (the minimum package that prevents ingress of microorganisms and allows aseptic presentation of the product at the point of use) and the protective packaging (configuration of materials designed to prevent damage to the sterile barrier system and its contents until the point of use).
subject of care	Any person who uses or is a potential user of a healthcare service, subjects of care may also be referred to as patients or healthcare consumers.
substrate	The material on which a barcode is printed or otherwise applied.
Supplemental symbol	A GS1-128 barcode used in combination with EAN/UPC, ITF-14 or GS1-128 where additional information is required beyond the barcode that carries the GS1 key (main symbol).
supplier	The party that produces, provides, or furnishes an item or service.
symbol character	A group of bars and spaces in a symbol that is decoded as a single unit. It may represent an individual digit, letter, punctuation mark, control indicator, or multiple data characters (see also codeword).
symbol check character	A symbol character or set of bar/space patterns included within a GS1-128 or GS1 DataBar symbol, the value of which is used by the barcode reader for the purpose of performing a mathematical check to ensure the accuracy of the scanned data. It is not shown in human readable interpretation. It is not input to the barcode printer and is not transmitted by the barcode reader.
symbol contrast	An <i>ISO/IEC 15416</i> parameter that measures the difference between the largest and smallest reflectance values in a Scan Reflectance Profile (SRP).
symbology	A defined method of representing numeric or alphabetic characters in a barcode; a type of barcode.
symbology identifier	A sequence of characters generated by the decoder (and prefixed to the decoded data transmitted by the decoder) that identifies the symbology from which the data has been decoded.
trade item	Any item (product or service) upon which there is a need to retrieve predefined information and that may be priced, or ordered, or invoiced at any point in any supply chain.
trade item declarations	The set of all information about a trade item (e.g., manufacturer warranty, ingredients, instructions for use, specifications, contents, certifications, predefined characteristics, and other information). For a trade item, this is all of the information that is on the label and in the original packaging. It also includes relevant aspects of the extended packaging.
trade item grouping	A predefined composition of trade item(s) that is not intended for point-of-sale scanning. It is identified with a GTIN-14, GTIN-13, or GTIN-12.
trade measures	Net measures of variable measure trade items as used for invoicing (billing) the trade item.
transport process information	A set of information relevant to the processing, delivery or return of a transport unit. For example, transport process information would include address details.
transport unit	A logistic unit within the context of transport processes.
truncation	Printing a symbol shorter than the symbology specification's minimum height recommendations. Truncation can make the symbol difficult for an operator to scan.

Release 24.0, Ratified, Jan 24

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Page 514 of 517