

GSMP:

General Specifications Change Notification (GSCN)

WR #	GSCN Name	Effective Date
18-265	Use of GS1 2D for fish and seafood	12-Dec-2018

Associated Work Request (WR) Number:

18-265

Background:

CEN is the European Committee for Standardization and brings together the National Standardization Bodies of 33 European countries. CEN has just issued a draft standard "prEN 17099 Fish and seafood products - Requirements for labelling of distribution units and pallets in the trade of fish and seafood products" which is now in enquiry stage and is expected to be published later this year. It features the use of GS1 standards throughout.

Currently, the GS1 standards only allow GS1-128 for distribution units. The Work Request aims to permit the use of a GS1 2D barcode symbol for distribution units.

Note: This change will require and update to the GS1 fish traceability guideline, which will be handled with a separate work request.

GS1 General Specification Change:

The recommended changes are highlighted below, relative to GS1 General Specifications version 18.

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AIDC marking level for regulated healthcare trade items	Кеу	Batch/lot number - AI (10)	Expiration date – AI (17)	Serial number – AI (21)	Other
Highest - Hospital AIDC marking of certain medical devices (see section 2.1.82.1.82.1.9)	GRAI, AI (8003), or GIAI, AI (8004), is optional if GTIN, AI (01), + serial number, AI (21), is not marked on the product.	No	No	GRAI, AI (8003), or GIAI, AI (8004), is optional if GTIN, AI (01), + serial number, AI (21), is not marked on the product.	

To manage healthcare data requirements within EPC/RFID tags, see section <u>3.11</u> and the most recent version of the *EPC Tag Data Standard*.

Optional

For compliance with a national/regional regulatory or industry requirement where the GTIN will not meet the need, a Regulated Healthcare Trade Item may be identified with GTIN and AI (710), AI (711), AI (712), AI (713), and AI (714) National Healthcare Reimbursement Number. See section <u>3.8.17</u> for details on the use of AI (710), AI (711), AI (712), AI (713), and AI (714).

Rules

National Healthcare Reimbursement Number AI (710), AI (711), AI (712), AI (713), and AI (714) must always be used with the GTIN.

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 2.1.52.1.52.1.6.

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

For regulated healthcare consumer trade items scanned in retail pharmacy and general distribution or non-retail pharmacy and general distribution see section <u>5.9.3.8</u>, GS1 symbol specification table 8.

For regulated healthcare retail consumer trade items not scanned in general distribution see section <u>5.9.3.10</u>, GS1 symbol specification table 10.

Symbol placement

All the symbol placement guidelines defined in section 6.

Unique application processing requirements

For a description of processing requirements, see section <u>7</u>.

2.1.82.1.7 Fixed measure tFrade items scanned inintended for general distribution scanning only

Every trade item that is different from another in any respect is assigned a unique Global Trade Item Number (GTIN). This includes trade item groupings of retail and non-retail trade items that are also trade items, and non-retail single units. For example, each of the packaging types in the figure below, if traded, is assigned a separate GTIN.

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Figure 2.1.7-1. Example of GTIN numbering options

Trade item	GTIN numbering options									
	GTIN-8	GTIN-12	GTIN-13	GTIN-14						
Single product A	Х	Х	Х							
50 x product A (Trade item grouping)		Х	Х	X						
50 x product A (Trade item grouping, e.g., display case)		Х	X	X						
100 x product A (Trade item grouping)		Х	X	X						
Single product B	Х	Х	Х							
50 x product A 50 x product B		х	Х							

If, at any time, the trade item is shipped or transported as an independent logistic unit, at the time of shipment it SHOULD additionally be identified with an SSCC. The combination of a GTIN and a serial number (also known as SGTIN) does not replace the SSCC as the identifier of a logistic unit.

2.1.8.12.1.7.1 Identification of a trade item that is a single product

Application description

The manufacturer or supplier has the option of assigning a unique GTIN-8, GTIN-12, GTIN-13 or in the case of regulated healthcare trade items and trade items used in manufacturing and maintenance, repair & overhaul (MRO) processes, a GTIN-14 to a trade item that is a single product as shown in figure 2.1.72.1.72.1.8-1. Restricted Circulation Numbers (RCNs) must not be used in this element string.

GS1 key

Definition <u>Required</u>	 Commented [CJ36]: WR18-cip1
The allowed key formats for this application are:	
 The GTIN-8 is the 8-digit GS1 identification key composed of a GS1-8 Prefix, item reference, and check digit used to identify trade items. 	
 The-GTIN-12 is the 12-digit GS1 identification key composed of a U.P.C. Company Prefix, item reference, and check digit used to identify trade items. 	
 The-GTIN-13 is the 13-digit GS1 identification key composed of a GS1 Company Prefix, item reference, and check digit used to identify trade items. 	
 For regulated healthcare trade items and trade items used in manufacturing and maintenance, repair & overhaul (MRO) processes: <u>the GTIN-14 is the 14-digit GS1 identification key</u> composed of an indicator digit (1-9), GS1 Company Prefix, item reference, and check digit used to identify trade items. 	
Rules	
See In addition to the GTIN rules described in section \underline{A} , the following guidelines should be observed: GTIN-8 can only be used when all other pack size constraints are met.	 Commented [CJ37]: WR18-cip3
Before deciding to use a GTIN-8 as opposed to a GTIN-12, GTIN-13, or in the case of regulated healthcare trade items, GTIN-14, companies, working jointly with their printer, should consider options such as:	
Whether the barcode can be reduced in size (e.g., printed at a lower X-dimension, taking into	 Formatted: GS1 Body

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Whether the label or artwork can reasonably be changed to enable the inclusion of an EAN-13 or a UPC-A barcode or a symbol from the GS1 DataBar Retail POS family.

-For example, redesigning the label and increasing the label size may be an option, especially when the existing label is small in comparison with the pack area.

 Whether a truncated barcode can be used. -

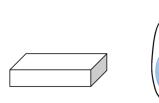
Note: A truncated barcode (normal length, but reduced in height) may only be used if there is absolutely no possibility of printing a full size barcode. Truncation removes the omnidirectional scanning capability. A barcode with excessive truncation will not be of any practical use. Users considering this option should consult their customers to see if an acceptable compromise can be reached.

Pack size constraints

The use of a GTIN-8 is authorised when:

- -The area of the largest label for the item is less than 40 cm², or
- -The product is cylindrical with a diameter less than 30 mm.

Figure 2.1.8.1-1. GTIN-8 pack size constraints





1. Total printable area 2. Largest label 3. Product diameter less than 80 cm2 less than 40 cm2 less than 30 mm

Attributes

Required

For regulated healthcare consumer trade items the following levels of AIDC marking are specified.

AIDC marking level for regulated healthcare trade items	Кеу	Batch/lot number - AI (10)	Expiration date – AI (17)	Serial number - AI (21)	Other
Minimum	GTIN-8, GTIN-12, GTIN-13, or GTIN-14	Yes	Yes	No	None
Enhanced	GTIN-8, GTIN-12, GTIN-13, or GTIN-14	Yes	Yes	No	None
Highest – Brand owner AIDC marking	GTIN-8, GTIN-12, GTIN-13, or GTIN-14	Yes	Yes	Yes	Potency AI (7004) for pharmaceutical, and for medical device kits with pharmaceutical (cases only for both situations)
Highest – Hospital AIDC marking of pharmaceutical	GTIN-8, GTIN-12, GTIN-13, or GTIN-14	No	AI (7003) for short-life products	Yes	None

Figure 2.1.7.1-112. Overview of required attributes

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AIDC marking level for regulated healthcare trade items	Кеу	Batch/lot number - AI (10)	Expiration date – AI (17)	Serial number - AI (21)	Other
Hospital AIDC marking of medical devices	No	No	No	No	None

To manage healthcare data requirements within EPC/RFID tags, see section <u>3.11</u> and the most recent version of the *EPC Tag Data Standard*.

Optional

Not applicable

Rules

Not applicable

Data carrier specification

Carrier choices

- Symbols from the EAN/UPC symbology family (UPC-A, UPC-E, may be used to encode the GTIN- ← − − 12, EAN-13 to encode the GTIN-13 and, if the size requirements are met, EAN-8 to encode the GTIN-8 of the trade item that is a single product).
- ITF-14 symbols may be used where printing conditions require the application of a less demanding symbology. ITF-14 symbols can encode the GTIN-12, or GTIN-13 of the item.
- A GS1-128 barcode or GS1 DataBar barcode (*) with GS1 Application Identifier (01) may be used to encode a GTIN that identifies the trade item if the printing conditions allow. The choice of one of these symbologies is particularly relevant if there is a need to encode attribute information in addition to the identification number.

Note: A GS1 DataBar barcode SHALL NOT be used to encode a GTIN-14 constructed from an ISBN.

(*) In 2014 GS1 DataBar became an open symbology and all scanning environments must be able to read these symbols.

Some scanning systems may be able to handle 2D barcodes as well as 1D barcodes. In these environments, 2D Symbols may be used in addition to linear symbols. For information on how to manage multiple barcodes (2.1.8) see section 4.16.

For trade items used in manufacturing and maintenance, repair & overhaul (MRO) processes the following data carrier choices take precedence over the carrier choices above: GS1-128, GS1 DataMatrix, GS1 QR Code and EPC/RFID.

For healthcare, the following carrier selections take precedence over the carrier choices above and apply to all regulated healthcare retail consumer trade items.

Figure 2.1.7.1-223. Healthcare carrier choices								
Preferred option(s) (this is the long-term direction for AIDC marking)	First preference: GS1-128 symbology. After Jan 2010, GS1 DataBar is permitted for use on all trade items and therefore may be encountered in general distribution however use of GS1-128 is preferred as the scanners in the field today pervasively support it.							
	Second preference: When one linear symbol cannot accommodate the field length of the data (exceeds 48 characters), two symbols should be used.							
	Third option: Where the package or label size does not permit the use of the first two options, GS1 DataMatrix symbology are permitted but should be avoided wherever possible if the package could be scanned by a mounted conveyorised scanner.							
Option in addition to the barcode	See the "data carrier specification carrier choices" recommendations on options in addition to the barcode at the end of section 2.1.52.1.52.1.6.							
Other acceptable options (GS1 strongly supports existing	See the "data carrier specification carrier choices" recommendations on other acceptable options found at the end of section $2.1.52.1.52.1.6$.							

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options for symbol marking as a guiding principle and therefore supports all previous AIDC marking	
specifications)	

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

For multi-sector use except for retail or regulated healthcare trade items see section <u>5.9.3.2</u>, GS1 symbol specification table 2.

For regulated healthcare non-retail consumer trade items see section <u>5.9.3.8</u>, GS1 symbol specification table 8.

For manufacturing and MRO processes see <u>5.9.3.4</u>, GS1 symbol specification table 4.

Symbol placement

All the symbol placement guidelines defined in section $\underline{6}$.

Unique application processing requirements

For a description of processing requirements, see section \underline{Z} .

2.1.8.22.1.7.2 Trade item groupings of identical trade items

Application description

A trade item grouping that is a predefined grouping of identical trade items. The manufacturer or supplier has the option of either assigning a unique GTIN-13 or GTIN-12 to each trade item grouping or assigning a unique GTIN-14. These 14-digit GTINs incorporate the GTIN (less its check digit) of the trade item contained in each grouping. The check digit for each GTIN-14 is then recalculated.

The indicators have no meaning. The digits do not have to be used in sequential order, and some may not be used at all. The GTIN-14 structure for trade item groupings creates extra numbering capacity. Indicators can be reused.

Figure 2.1.7.2-1. GTIN-14 data structures														
	Global Trade Item Number (GTIN)													
	Indicator		GTIN of contained trade items Check (without check digit) digit											
GTIN-8 based	N1	0	0	0	0	0	N ₇	N ₈	N9	N_{10}	N_{11}	N_{12}	N ₁₃	N ₁₄
GTIN-12 based	N1	0	N_3	N_4	N_5	N_6	N ₇	N_8	N ₉	N_{10}	N_{11}	N_{12}	N ₁₃	N ₁₄
GTIN-13 based	N1	N ₂	N3	N_4	N5	N ₆	N7	N ₈	N9	N10	N ₁₁	N ₁₂	N13	N14

The indicator is a digit with a value of 1 to 8. It is assigned as required by the company that constructs the identification number. It can provide up to eight separate GTIN-14s to identify trade item groupings.

For packaging configuration hierarchies which include a retail consumer trade item identified with a GTIN-13, GTIN-12, or GTIN-8, this GTIN must always be one of the relevant levels of packaging contained, usually the lowest level (see note below related to GTIN-14 assignment on the primary packaging). Restricted Circulation Numbers must not be used in this element string.

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Note: For regulated healthcare trade items on the primary packaging, the phrase "usually the lowest level" SHALL be interpreted as allowing for the use of GTIN-14 on packaging configurations below the retail consumer trade item level, if one exists. This interpretation may not be applied to other trade item categories such as Do It Yourself (DIY) or Foodservice.

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Any product package which will encounter scanning or product listing for sale at point-of-sale SHALL ____ Com above identified according to retail point-of-sale specifications.

When a GTIN change at the retail consumer trade item level is required, the GTIN change must be made at all configuration levels above the retail consumer trade item level. Where there is an association between primary packaging and retail consumer trade item levels and GTIN -14 assignment is used on the primary packaging, the GTIN-14 assigned to the primary packaging is based on the retail level GTIN. There are three scenarios to consider for the relationship of these GTIN assignments:

- If changes to the primary packaging drive the change of the GTIN assigned to the retail consumer trade item level, the GTIN of the primary packaging will change.
- If changes to retail consumer trade item level GTIN are not caused by a change in primary packaging, the GTIN at the primary package level may or may not change per the discretion of the brand owner.
- If additional retail level package(s) are introduced beyond the original retail package or replace the original retail package, the GTIN-14 on the primary packing may remain tied to the original retail level GTIN.

The check digit is explained in section $\underline{7.9}$. Its verification, usually carried out automatically by the barcode reader, ensures that the number is correctly composed.

Figure 2.1.7.2-2. Different groupings of the same trade item

Indicator	GTIN of trade item contained in the grouping, less its check digit	New check digit	Description	Quantity	
	061414112345	2	Trade item	Single	
1	061414112345	9	Trade item grouping	A grouping	
8	061414112345	8	Trade item grouping	Another grouping	

Indicators 1 to 8 may be used to create new GTIN-14s. When these eight indicators have been used, further groupings must be identified with either a GTIN-13 or GTIN-12. (Indicator digit 9 is reserved for variable measure trade items). (See section 2.1.5).

GS1 key

DefinitionRequired

The allowed key formats for this application are:

- The GTIN-8-is the 8-digit GS1 identification key composed of a GS1-8 Prefix, item reference, and check digit used to identify trade items
- The GTIN-12 is the 12 digit GS1 identification key composed of a U.P.C. Company Prefix, item reference, and check digit used to identify trade items.
- The GTIN-13 is the 13-digit GS1 identification key composed of a GS1 Company Prefix, item reference, and check digit used to identify trade items.
- The GTIN-14 is 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.

Rules

All the GTIN rules described in section 4.2.1.

Attributes

Required

For regulated healthcare consumer trade items the following levels of AIDC marking are specified:

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Figure 2.1.7.2-3. Required attributes

rigure ziii/iz 5. Required attributes									
AIDC marking level for regulated healthcare trade items	Key	Batch/lot number - AI (10)	Expiration date – AI (17)	Serial number – AI (21)	Other				
Minimum	GTIN-8, GTIN- 12, GTIN-13, or GTIN-14	Yes	Yes	No	None				
Enhanced GTIN-8, GTIN 12, GTIN-13, GTIN-14		Yes	Yes	No	None				
Highest – Brand owner AIDC marking	GTIN-8, GTIN- 12, GTIN-13, or GTIN-14	Yes	Yes	Yes	Potency AI (7004) for pharmaceutical, and for medical device kits with pharmaceutical (cases only for both situations)				
Highest – Hospital AIDC marking of pharmaceutical	GTIN-8, GTIN- 12, GTIN-13, or GTIN-14	No	AI (7003) for short- life products	Yes	None				
Hospital AIDC marking of medical devices	No	No	No	No	None				

To manage healthcare data requirements within EPC/RFID tags, see section <u>3.11</u> and the most recent version of the *EPC Tag Data Standard*.

Optional

Not applicable

Rules

Not applicable

Data carrier specification

Carrier choices

- For multi-sector use symbols from the EAN/UPC symbology family (UPC-A, UPC-E, and EAN-13) ← may be used to encode the GTIN-12 or GTIN-13 of the trade item grouping. If used, the GTIN-8 is encoded in an EAN-8 barcode. GTIN-8 can only be used when all other pack size constraints are met, see section <u>2.1.3.44.3.7</u>. The system recognises this element string by the symbology identifier **]EO**.
- ITF-14 symbols may be used on trade item groupings where printing conditions require the application of a less demanding symbology. ITF-14 symbols can encode the GTIN-12, GTIN-13, or GTIN-14 of the item. The system recognises this element string by the symbology identifier **J11** and the number of digits decoded (14).
- A GS1-128 barcode or GS1 DataBar barcode (*) with GS1 Application Identifier (01) may be used to encode a GTIN-12, GTIN-13, or GTIN-14 that identifies the trade item if the printing conditions allow. The choice of one of these symbologies is particularly relevant if there is a need to encode attribute information in addition to the identification number. The system recognises this element string by the symbology identifier (**]C1** for GS-128, **]e0** for GS1 DataBar) and the GS1 application identifier.

Note: A GS1 DataBar barcode SHALL NOT be used to encode a GTIN-14 constructed from an ISBN.

(*) In 2014 GS1 DataBar became an open symbology and all scanning environments must be able

to read these symbols. ______ Commented [CJ45]: WR18-cip2 _____ Commented [CJ46]: WR18-cip2 ______ Commented [CJ46]: WR18-cip2 _______ Commented [CJ46]: WR18-cip2 ________ Commented [CJ46]: WR18-cip2 ________ Commented [CJ46]: WR18-cip2 ________ Commented [CJ46]: WR18-cip2 ________ Commented [CJ46]: WR18-cip2 _________ Commented [CJ46]: WR18-cip2 _________ Commented [CJ46]: WR18-cip2 ________ Commented [CJ46]: WR18-cip2 ________ Commented [CJ46]: WR18-cip2 ________ Commented [CJ46]: WR18-cip2 _________ Commented [CJ46]: WR18-cip2 _________ Commented [CJ46]: WR18-cip2 __________ Commented [CJ46]: WR18-cip2 _________COM ________ Commented [CJ46]: WR18-

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For trade items used in manufacturing and maintenance, repair & overhaul (MRO) processes the following data carrier choices take precedence over the carrier choices above: GS1-128, GS1 DataMatrix, GS1 QR Code and EPC/RFID.

For healthcare the carrier selections noted at the end of section <u>2.1.7.12.1.7.12.1.8.1</u> take precedence over the carrier choices above and apply to all regulated healthcare retail consumer trade items.

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

For multi-sector use other than regulated healthcare trade items see section <u>5.9.3.2</u>, GS1 symbol specification table 2.

For regulated healthcare non-retail consumer trade items see section <u>5.9.3.8</u>, GS1 symbol specification table 8.

For manufacturing and MRO processes see <u>5.9.3.4</u>, GS1 symbol specification table 4.

Symbol placement

All the symbol placement guidelines defined in section $\underline{6}$.

Unique application processing requirements

For a description of processing requirements, see section <u>Z</u>.

2.1.8.32.1.7.3 Trade item groupings of mixed trade items

Application description

A trade item grouping that is a predefined grouping of two or more different trade items. For example:

- Product C is a grouping of Product A (GTIN 'A') and Product B (GTIN 'B'), and is identified with either a GTIN-12 or GTIN-13, GTIN 'C.'
- GTIN 'C' could then be used to construct a GTIN-14 for a trade item grouping comprised of Product C.

As shown in figure 2.1.7.32.1.7.32.1.8.3-1, the GTIN-12s 614141234561 and 614141345670 identify the two trade items in the assortment identified by the GTIN 614141456789.

Figure 2.1.7.3-1. Example of	of trad	e item	aroupina	of mixed	trade items
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Indicator	GTIN of trade item less its check digit	Check digit Description		Quantity		
	061414123456 061414134567	1 0	Retail consumer trade item (Product A) Retail consumer trade item (Product B)	Single Single		
	061414145678	9	Retail consumer trade item (Product C)	Assortment		
1	061414145678	6	Trade item grouping	A grouping of the assortment		
8	061414145678	5	Trade item grouping	Another grouping of the assortment		
			N-14s. When these eight indicato r GTIN-12. (Indicator digit 9 is re			

measure trade items). (See section 2.1.5).

GS1 key

Definition Required

The allowed key formats for this application are:

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- The GTIN-12 is the 12-digit GS1 identification key composed of a U.P.C. Company Prefix, item reference, and check digit used to identify trade items.
- The GTIN-13 is the 13-digit GS1 identification key composed of a GS1 Company Prefix, item reference, and check digit used to identify trade items.
- The GTIN-14 is 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

Rules

All the GTIN rules described in section <u>4.2.1</u>; in addition, the GTIN-14 is valid for trade item groupings only when the trade item contained is a mixed assortment of two or more different trade items.

Attributes

Required

Not applicable

Optional

Not applicable

Data carrier specification

Carrier choices

- Symbols from the EAN/UPC symbology family (UPC-A, UPC-E, and EAN-13) may be used to encode the GTIN-12 or GTIN-13 of the trade item grouping. The system recognises this element string by the symbology identifier **]EO**.
- ITF-14 symbols may be used on trade item groupings where printing conditions require the application of a less demanding symbology. ITF-14 symbols can encode the GTIN-12, GTIN-13, or GTIN-14 of the item. The system recognises this element string by the symbology identifier II and the number of digits decoded (14).
- A GS1-128 barcode or GS1 DataBar barcode (*) with GS1 Application Identifier (01) may be used to encode a GTIN-12, GTIN-13, or GTIN-14 that identifies the trade item if the printing conditions allow. The choice of one of these symbologies is particularly relevant if there is a need to encode attribute information in addition to the identification number. The system recognises this element string by the symbology identifier (**]C1** for GS1 128, **]e0** for GS1 DataBar) and the GS1 Application Identifier.

Note: A GS1 DataBar barcode SHALL NOT be used to encode a GTIN-14 constructed from an ISBN.

(*) In 2014 GS1 DataBar became an open symbology and all scanning environments must be able to read these symbols.

Some scanning systems may be able to handle 2D barcodes as well as 1D barcodes. In these environments, 2D Symbols may be used in addition to linear symbols. For information on how to manage multiple barcodes (2.1.8) see section 4.16.

For trade items used in manufacturing and maintenance, repair & overhaul (MRO) processes the following data carrier choices take precedence over the carrier choices above: GS1-128, GS1 DataMatrix, GS1 QR Code and EPC/RFID.

For healthcare, the carrier selections noted at the end of section <u>2.1.7.12.1.7.12.1.8.1</u> take precedence over the carrier choices above and apply to all regulated healthcare retail consumer trade items.

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

For multi-sector use other than regulated healthcare trade items see section <u>5.9.3.2</u>, GS1 symbol specification table 2.

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For regulated healthcare non-retail consumer trade items see section <u>5.9.3.8</u>, GS1 symbol specification table 8.

For manufacturing and MRO processes see <u>5.9.3.4</u>, GS1 symbol specification table 4.

Symbol placement

All the symbol placement guidelines defined in section $\underline{6}$.

Unique application processing requirements

For a description of processing requirements, see section Z.

2.1.92.1.8 Medical devices (non-retail trade items)

Application description

Within this application are the rules and recommendations for the direct part marking (DPM) of medical devices for the Automatic Identification and Data Capture (AIDC) management, including medical devices that are reprocessed (within the micro-logistics cycle of use, including cleaning and sterilisation).

Medical devices SHOULD be identified with GTIN and any appropriate GS1 Application Identifiers used for production control, as determined by the responsible entity for the device. For medical devices that are reprocessed, GTIN and serial number are recommended for manufacturers that use DPM to enable traceability throughout the product lifecycle.

Also, for hospitals or instrument owners that mark medical devices that are reprocessed, GTIN and serial number are recommended for all hospital/instrument owner marking. Some existing in-house legacy systems already use GS1 asset identifiers (GIAI or GRAI, see section <u>2.3</u>), which are compliant with GS1 standards.

Note: Only one GS1 key (GTIN or GIAI/GRAI) SHOULD be marked on a single instrument.

GS1 key

Definition Required

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The allowed key formats for this application are:

- The GTIN-12 is the 12 digit GS1 identification key composed of a U.P.C. Company Prefix, item reference, and check digit used to identify trade items.
- The GTIN-13-is the 13-digit GS1 identification key composed of a GS1 Company Prefix, item reference, and check digit used to identify trade items.
- The GTIN-14-is 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.
- The GRAI-is the GS1 identification key used to identify returnable assets. The key is comprised of a GS1 Company Prefix, asset type, check digit, and optional serial number.
- The GIAI is the GS1 identification key used to identify an individual asset. The key is comprised of a GS1 Company Prefix and an individual asset reference.

Rules

- All the GTIN rules described in section <u>4.2.1</u>.
- All the GIAI and GRAI application rules described in section <u>4.2.3</u>.
- If the AIDC marking on the medical device may be seen and scanned when placed in the
 protective packaging after sterilisation, the protective packaging will not have to be AIDC
 marked.

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4.16 Multiple barcode management practices for consumer trade items (crosssector)

When additional barcodes are introduced into an existing scanning environment or business application existing barcodes must remain acceptable while migration secures. EAN/UPC symbols _ _ _ have been used for POS/POC and will continue to be used for existing applications however new symbologies have been introduced to support new application requirements. Until all parties can process GTIN using the new technologies, existing technology must be supported while new technology migration occurs. This sectionstandard provides a set of management practices intended to permit the use of existing and new technologiesmultiple barcodes on the sameone package, in order to avoid the need for separate inventories.

In addition to supporting POS/POC and general distribution scanning applications, consumer trade item packages may now support additional business processes using barcodes. For example, support for B2C extended packaging and trade item production control. For this reason, a management practices has been introduced to separate, where possible, symbols for different functions and in the case of production control barcodes, another management practice is introduced to obstruct their supply chain scanning or make them obscure where possible.

The transition to use of additional data beyond GTIN in barcodes is a non-trivial step for the retail and healthcare industry. It means operators must learn to handle the new technologies and systems must be adapted to process them. The management practices were designed after considering the different types of scanner systems, testing over 170 symbols combinations, and the ways each interact with each other and the operator.

In section <u>4.16.1</u>, practices 1, 6, and 7 apply now and in the future. Section <u>4.16.2</u>, practice 1 and section <u>4.16.3</u>, practice 1 and 2, once implemented, will eliminate the need for section <u>4.16.1</u> practices 2–5 as they are present to support a migration period.

4.16.1 Multiple barcode management practices for consumer trade items (all sectors)

- Current standards: All scanning systems SHALL deploy symbology identifiers (see section <u>5.1.2</u>) and when using GS1 Application Identifiers, process them according to GS1 rules (see section <u>7.8</u>).
- GTIN plus attribute(s) flag: Where applications require additional data be captured in a multiple barcode symbol environment, modifications to systems should be made to automate this requirement to optimise efficiency.
- 3. Adjacent placement: Wherever two symbols can be used for the same application (POS, POC, general distribution) they SHOULD be placed adjacent to one another. Adjacent placement of symbols SHALL never infringe on symbol Quiet Zones. The orientation (stack or row of symbols) or sequence (which symbol is placed on the left, right, top, or bottom) and shall be determined by the brand owner. Where adjacent placement on one panel is not permitted based on space limitations, placement on adjacent panels SHOULD be attempted. This practice does not supersede any section <u>6</u> symbol placement rule (e.g.,: 8_mm (0.3_inch) free space between symbols and panel edge.)
- Non-adjacent placement: Wherever two symbols are used for different applications (POS, B2C <u>e</u>Extended <u>p</u>Packaging (EP) Direct Mode), they SHOULD be placed non-adjacent to one another.
- Obscure placement: Wherever a symbol is used for production control purposes only, it SHOULD be made as obscure as possible or even obstructed on the consumer trade item package.
- Product URL barcode indication: For barcodes encoding AI (01) (8200) see section <u>4.15</u> Human readable interpretation rules, rule 9.)
- 7. Use of GS1-128 or GS1 2D symbol-use as secondary symbol withwhen EAN/UPC or ITF-14 as the primary symbolis required. In general distribution, where EAN/UPC and/or ITF-14 is used to encode the GTIN and where a GS1-128 /GS1 2D symbol is used to encode GTIN attributes, the GTIN SHOULD SHALL also be encoded in the GS1-128 encoding GTIN attributes but GTIN is not required based on previous standards based implementationsall GS1 symbols.

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Use of GS1 2D symbol as secondary symbol with GS1-128 as primary symbol: In general distribution, where GS1-128 is used to encode GTIN and attributes, these element strings at a minimum SHALL be encoded in the GS1 2D symbol.



Note: Where GS1 DataBar and GS1 DataMatrix are used, GTIN and GTIN attributes shall be concatenated to ensure accurate data association.

4.16.2 GS1 multiple barcode management practice for general retail

 GTIN in GS1 DataBar processing: In order to facilitate migration away from a multiple barcode environment where one retailer requires EAN/UPC and another GS1 DataBar Expanded, at a minimum, all general retailers SHALL be able to process the AI (01) GTIN from GS1 DataBar Expanded.

4.16.3 GS1 multiple barcode management practices for healthcare

- GTIN in GS1 DataMatrix and GS1 DataBar processing (retail healthcare): In order to facilitate migration away from a multiple barcode environment where one retail pharmacy requires EAN/UPC and another retail pharmacy requires GS1 DataMatrix or GS1 DataBar Expanded, at a minimum, retail pharmacies SHALL have the capability to process the AI (01) GTIN from GS1 DataMatrix and GS1 DataBar in addition to the capability for EAN/UPC.
- 2. GTIN in GS1 DataMatrix, GS1 DataBar, and GS1-128 processing (non-retail healthcare): In order to facilitate migration away from a multiple barcode environment where one healthcare provider requires EAN/UPC or ITF-14 and another healthcare provider requires GS1 DataMatrix, GS1 DataBar Expanded, or GS1-128, at a minimum, non-retail pharmacies SHALL have the capability to process AI (01) GTIN from GS1 DataMatrix, GS1 DataBar, and GS1-128 in addition to the capability for EAN/UPC and ITF-14.
- 3. GS1-128 as secondary symbol: In point-of-care applications, where EAN/UPC or ITF-14 is used to encode GTIN and where GS1-128 is used to encode GTIN attributes, GS1-128 SHOULD encode GTIN as it is best practice to encode the GTIN attributes and the GTIN in a single symbol whenever possible to ensure accurate data association.

Note: Where GS1 DataBar and GS1 DataMatrix are used, GTIN and GTIN attributes SHALL be concatenated to ensure accurate data association.

- 4. Scenario-based management practices: Multiple barcode practices which apply to all sectors are found in section <u>4.16.1</u> and take precedence over those specific only to healthcare. While industry best practice focuses on using only one barcode per package, a product package that serves multiple markets may have the need for application of multiple barcodes. When this occurrence is unavoidable, the management practices for use of multiple symbols found in figure <u>4.16.3-1</u> apply for regulated healthcare trade items. The figure separates solutions based on combinations of scanner environments encountered for each scenario:
 - □ Scanners encountered combination #1: Package scanned in retail pharmacies (Yes or No).
 - Scanners encountered combination #2: Package scanned in general distribution (Yes or No).

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5.9.3.2 Symbol specification table 2 - Trade items scanned in general distribution only

Symbol(s) specified	(*) X-dimension mm (inches)			(**) Minimum symbol height for given X mm (inches)			Quiet Zone		(***) Minimum quality specification	
	Minimum	Target	Maximum	For minimu m X- dimensi on	For target X- dimension	For maximum X-dimension	Left	Right		
EAN-13	0.495 (0.0195")	0.660 (0.0260")	0.660 (0.0260")	34.28 (1.350")	45.70 (1.800")	45.70 (1.800")	11X	7 <i>X</i>	1.5/10/660	
EAN-8	0.495 (0.0195")	0.660 (0.0260")	0.660 (0.0260")	27.35 (1.077")	36.46 (1.435")	36.46 (1.435")	7 <i>X</i>	7 <i>X</i>	1.5/10/660	
UPC-A	0.495 (0.0195")	0.660 (0.0260")	0.660 (0.0260")	34.28 (1.350")	45.70 (1.800")	45.70 (1.800")	9 <i>X</i>	9 <i>X</i>	1.5/10/660	
UPC-E	0.495 (0.0195")	0.660 (0.0260")	0.660 (0.0260")	34.28 (1.350")	45.70 (1.800")	45.70 (1.800")	9 <i>X</i>	7X	1.5/10/660	
ITF-14	0.495 (0.0195")	0.495 (0.0195")	1.016 (0.0400")	31.75 (1.250")	31.75 (1.250")	31.75 (1.250")	10X	10 <i>X</i>	1.5/10/660	
GS1-128	0.495 (0.0195")	0.495 (0.0195")	1.016 (0.0400")	31.75 (1.250")	31.75 (1.250")	31.75 (1.250")	10X	10 <i>X</i>	1.5/10/660	
GS1 DataBar Omni- directional	0.495 (0.0195")	0.660 (0.0260")	0.660 (0.0260")	16.34 (0.644")	21.78 (0.858″)	21.78 (0.858″)	NA	NA	1.5/10/660	
GS1 DataBar Stacked Omni- directional	0.495 (0.0195")	0.660 (0.0260")	0.660 (0.0260")	34.16 (1.346″)	45.54 (1.794″)	45.54 (1.794″)	NA	NA	1.5/10/660	
GS1 DataBar Expanded	0.495 (0.0195")	0.660 (0.0260")	0.660 (0.0260")	16.83 (0.663")	22.44 (0.884")	22.44 (0.884")	NA	NA	1.5/10/660	
GS1 DataBar Expanded Stacked	0.495 (0.0195")	0.660 (0.0260")	0.660 (0.0260")	35.15 (1.385″)	46.86 (1.846″)	46.86 (1.846")	NA	NA	1.5/10/660	
GS1 DataBar Stacked	0.495 (0.0195")	0.660 (0.0260")	0.660 (0.0260")	6.44 (0.254″)	8.58 (0.338″)	8.58 (0.338″)	NA	NA	1.5/10/660	
GS1 DataBar Limited	0.495 (0.0195")	0.660 (0.0260")	0.660 (0.0260")	4.95 (0.195″)	6.60 (0.260″)	6.60 (0.260″)	NA	NA	1.5/10/660	
GS1 DataBar Truncated	0.495 (0.0195")	0.660 (0.0260")	0.660 (0.0260")	6.44 (0.254″)	8.58 (0.338″)	8.58 (0.338″)	NA	NA	1.5/10/660	
<u>GS1</u> DataMatrix (ECC 200) (****)	<u>0.743</u> <u>(0.0292)</u>	<u>0.743</u> (0.0292")	<u>1.50</u> (0.0591)	Height is determined by X-dimension and data that is encoded			<u>1X on all four</u> sides		1.5/20/660	
<u>GS1 QR</u> <u>Code</u> (****)	<u>0.743</u> (0.0292)	<u>0.743</u> (0.0292)	<u>1.50</u> (0.0591)	Height is determined by X-dimension and data that is encoded				<u>all four</u> des	<u>1.5/20/660</u>	

Figure 5.9.3.2-1. GS1 symbol specification table 2

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UPC-E and EAN-8 symbols are designed for use on small packages. Whenever space permits, UPC-A, EAN-13, ITF-14, or GS1-128 symbols SHOULD be used in the gGeneral distribution scanning environment. The minimum symbol height dimensions listed for all symbologies including EAN/UPC symbols do not include the human readable interpretation (or bearer bars for ITF-14 symbols). The minimum heights of EAN/UPC symbols do not include the extended bars: see section <u>5.2.3.2</u> for dimensions of the extended bars. Because of the operative scanning environment for EAN/UPC symbols, there is a direct relationship between the symbol's height and width. This means the minimum symbol height is tied to the minimum, target, and maximum X-dimension listed.

ITF-14 symbols with X-dimensions below 0.635 millimetre (0.0250 inch) SHOULD NOT be printed directly on corrugate with conventional (plate-based) processes. The ITF-14 symbol's bar width ratio target is 2.5:1, and the acceptable range is 2.25:1 to 3:1.

GS1-128 symbols have a maximum symbol length of 165.10 millimetres (6.500 inch), which may impact the maximum achievable X-dimension. For example, a GS1-128 symbol containing an SSCC has a maximum achievable X-dimension for 0.940 millimetre (0.0370 inch)

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GS1 General Specifications

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	For GS1-128 and ITF-14, a smaller X-Dimension may be used if there is absolutely no possibility of printing the Fullminimum size barcode because the trade item is physically too small; the X-Dimension SHALL NOT be less than 0.250 millimetre (0.0098 inch). For details on barcode production and quality assessment see section 5.9.
(**)	For GS1-128 and ITF-14 symbols the minimum symbol height for General distribution scanning is always 31.75 millimetres (1.250 inch). The minimum symbol height dimensions relate to the bar heights only (do not include human readable interpretation text or ITF-14 symbol bearer bars).
	If the trade item is physically too small to accommodate the minimum, for GS1-128 and ITF-14 the minimum height can be reduced to 12.70 millimetres (0.500 inch) or in case of further space constraints to no less than 5.08 millimetres (0.200 inch). For details on barcode production and quality assessment see section 5.9 .
	There is no maximum for the height, but if the maximum X-dimension is used, the symbol height must be equal to or greater than those listed in the Minimum Symbol Height column.
(***)	For ITF-14 symbols printed on labels with off-set, thermal, or laser print with an X-dimension 0.495 millimetre (0.0195 inch), the minimum quality specification is 1.5/10/660. For ITF-14 symbols printed directly on corrugate or labels with an X-dimension greater than or equal to 0.635 millimetre (0.0250 inch), the minimum quality specification is 0.5/20/660.
<u>(****)</u>	2D X-dimension - Optical effects in the image capture process require that the GS1 DataMatrix and GS1 QR Code symbols be printed at 1.5 times the equivalent printing X-dimension allowed for linear symbols.

5.9.3.3 Symbol specification table 3 - Trade items scanned at general retail POS and general distribution

Symbol(s) specified	(*) X-dimension mm (inches)			(**) Minimum symbol height for given X mm (inches)			Quiet Zone		Minimum quality specification
	Minimum	Target		For minimum X- dimension	For target X- dimension	For maximum X-dimension	Left	Right	
EAN-13	0.495 (0.0195")	0.660 (0.0260")	0.660 (0.0260")	34.28 (1.350")	45.70 (1.800")	45.70 (1.800")	11X	7X	1.5/06/660
EAN-8	0.495 (0.0195")	0.660 (0.0260")	0.660 (0.0260")	27.35 (1.077")	36.46 (1.435")	36.46 (1.435")	7X	7X	1.5/06/660
UPC-A	0.495 (0.0195")	0.660 (0.0260")	0.660 (0.0260")	34.28 (1.350")	45.70 (1.800")	45.70 (1.800")	9 <i>X</i>	9 <i>X</i>	1.5/06/660
UPC-E	0.495 (0.0195")	0.660 (0.0260")	0.660 (0.0260")	34.28 (1.350")	45.70 (1.800")	45.70 (1.800")	9 <i>X</i>	7X	1.5/06/660
GS1 DataBar Omni- directional (***)	0.495 (0.0195")	0.660 (0.0260")	0.660 (0.0260")	22.77 (0.897″)	30.36 (1.196″)	30.36 (1.196″)	None	None	1.5/06/660
GS1 DataBar Stacked Omni- directional (***)	0.495 (0.0195")	0.660 (0.0260")	0.660 (0.0260")	47.03 (1.853″)	62.70 (2.470″)	62.70 (2.470″)	None	None	1.5/06/660
GS1 DataBar Expanded	0.495 (0.0195")	0.660 (0.0260")	0.660 (0.0260")	16.83 (0.663")	22.44 (0.884")	22.44 (0.884")	None	None	1.5/06/660
GS1 DataBar Expanded Stacked	0.495 (0.0195")	0.660 (0.0260")	0.660 (0.0260")	35.15 (1.385")	46.86 (1.846")	46.86 (1.846″)	None	None	1.5/06/660

Figure 5.9.3.3-1. GS1 symbol specification table 3

(*) UPC-E and EAN-8 symbols are designed for use on small packages. Whenever space permits, UPC-A and EAN-13 symbols SHOULD be used.

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