



WR #	GSCN Name	Effective Date
21-000287	GS1 General Specifications Healthcare Minimum AIDC marking revision	Nov-2021

Associated Work Request (WR) Number:

N/A

Background:

There are currently three tables within the General Specifications that detail incorrect minimum AIDC marking levels for regulated healthcare products. These tables each detail the minimum marking level to include the GTIN, Batch Number and Expiration Date when in fact the minimum marking level is for the GTIN only.

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2.1.6 Healthcare secondary packaging (regulated healthcare retail consumer trade items)

A regulated healthcare retail consumer trade item not intended to be scanned in high volumes per consumer transaction at retail, but does require additional data beyond GTIN to support regulatory requirements. This means, these trade items support:

- GTIN-8, GTIN-12, or GTIN-13 data structures.
- GTIN attributes such as batch/lot number, expiration dates, or serial numbers.

They may be marked with 2D matrix barcodes that require imaging-based scanners or linear symbologies such as GS1 DataBar or GS1-128. If an item is a general retail consumer trade item and regulated healthcare retail consumer trade item, then the barcode marking for general retail is required at a minimum.

GS1 key

Required

The allowed key formats for this application are:

- GTIN-8
- GTIN-12
- GTIN-13

GS1 firmly endorses the use of GTIN in all markets, however there are instances where GS1 Member Organisations have allocated a portion of their numbering capacity to identification schemes administered nationally by external agencies.

These coding schemes while recognised within the GS1 system framework by the assignment of a GS1 Prefix are defined, in Healthcare, as National Trade Items Numbers (NTINs) rather than Global Trade item Numbers (GTINs). NTINs are unique with respect to GTINs as their values are a subset of all possible values of GTIN. However, their definition, allocation and lifecycle rules are defined by an organisation external to GS1.

The degree to which NTIN definitions and rules are compatible with those of GTIN is specific to each national definition. Whilst NTIN will always provide globally unique identification within the GTIN pool of numbers, this does not mean NTIN provides the same level of interoperability as GTIN with other GS1 standards, such as GDSN and ONS. In markets where NTIN is adopted exclusively of GTIN, the reciprocal nature of GTIN identification and marking across markets is lost and becomes problematic where one package which should serve multiple markets (e.g., common language) requires multiple NTINs rather than one GTIN.

Rules

See the GTIN rules in section [4.3](#).

Attributes

Required

Figure 2.1.6-1. Overview of 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 - Pharmaceutical & medical device	GTIN-8, GTIN-12, or GTIN-13	Yes/No	Yes/No	No	None
Enhanced - Pharmaceutical & medical device	GTIN-8, GTIN-12, or GTIN-13	Yes	Yes	No	None



Attributes

Required

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

Figure 2.1.7.1-1. Overview of 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	YesNo	YesNo	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
Hospital AIDC marking of medical devices	No	No	No	No	None

To manage healthcare data requirements within EPC/RFID tags, see section [3.11](#) 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.

Some scanning systems may be able to handle 2D barcodes as well as linear barcodes. In these environments, GS1 2D symbols may be used in addition to linear symbols. For information on how to manage multiple barcodes 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.



Rules

All the GTIN rules described in section [4](#).

Attributes

Required

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

Figure 2.1.7.2-3. 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	YesNo	YesNo	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
Hospital AIDC marking of medical devices	No	No	No	No	None

To manage healthcare data requirements within EPC/RFID tags, see section [3.11](#) 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-E₇ 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 packaging size constraints are met, see section [4.3.7](#).
- 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.
- 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.

Some scanning systems may be able to handle 2D barcodes as well as linear barcodes. In these environments, GS1 2D symbols may be used in addition to linear symbols. For information on how to manage multiple barcodes 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.