WR #	GSCN Name	Effective Date	
WR 23-291	Clarification of wording related to encoding GMN in a data carrier	Dec 2023	

Associated Work Request (WR) Number:

Background:

There is somewhat confusing and potentially conflicting guidance on when or if a GMN is encoded in a data carrier. This request seeks to eliminate the confusion. The only change in this work request is deleting the **highlighted text**. Other sections/text appear for context purposes.

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GS1 General Specifications Standard

2.6.13 Global Model Number (GMN)

Application description

The GS1 Global Model Number (GMN) is the GS1 identification key that may be used to identify a product model (e.g., or medical device product family, apparel style, consumer electronic model) based on attributes common to the model or family as defined by the brand owner in accordance with industry guidelines (where available) or regulation. The A product model is the basis from which related trade items are devived. GMN comprises the GS1 Company Prefix, a model reference and check character pair. The model reference utilises characters from GS1 AI encodable character set 82 and its structure is left to the discretion of the brand owner who assigns it. (see section 3.9.13)

This GS1 identification key, once assigned to one product model or product family, SHALL NOT be reissued to another product model. The GMN SHALL NOT be used to identify a trade item. <u>A GMN is an attribute of a trade item identified with a GTIN. A GMN is directly correlated to one or more GTINs, a GTIN SHALL only be associated with one GMN.</u>

The Global Model Number can be used by any industry but for regulated healthcare medical devices the following applies:

Regulated healthcare medical devices

For regulated healthcare medical devices, the GMN is the GS1 identification key to support the implementation of the Basic UDI-DI requirements.

For regulated healthcare medical devices, the Basic UDI-DI serves as the key element in the UDI regulatory database for medical devices.

By providing an identifier for a medical device product family, the GMN will link medical device trade item(s) identified by GTIN(s) in the UDI database to pre-market and post-market activities (e.g., certificates, declaration of conformity, vigilance, market surveillance and clinical investigations).

The following points highlight the relationship between Basic UDI-DI (GMN) and UDI-DI (GTIN.)

- Basic UDI-DI (GMN) is used for medical device registration and is assigned independent of packaging/labelling and is different from the identifier for trade items in the supply chain (UDI-DI(GTIN)).
- All Basic UDI-DI (GMN) level attributes (in the UDI regulatory database) are common for all GTINs associated with it.
- All attributes across all UDI-DIs (GTINs) associated with one Basic UDI-DI (GMN) may not be common.
- The Basic UDI-DI (GMN) is used for device registration in the registration database. The UDI-DI (GTIN) is used for trade item identification in the UDI database. UDI-DI (GTIN) and Basic UDI-DI (GMN) allocation may occur before, in parallel, or after each other and attribution and/or linkage between the entities is only possible once both entities exist. For this reason, allocation of UDI-DI (GTIN) and Basic UDI-DI (GMN) shall be made independent of one another.
- Brand owners are responsible for the assignment of Basic UDI-DI (GMN) and UDI-DI (GTIN.)

GS1 key

Required

GMN

The GS1 Application Identifier to indicate the Global Model Number is AI (8013), see section 3.2.

Rules

See section 4.12.

- The Global Model Number SHALL NOT be used as a replacement for the GTIN.
- The GTIN SHALL NOT be used as a replacement for the Global Model Number.

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For regulated healthcare medical devices, the following applies:

- At any given time, the relationship between Basic UDI-DI (GMN) and UDI-DI (GTIN) is 1:n (can be one to one or one to many), meaning a Basic UDI-DI (GMN) can be related to more than one UDI-DI (GTIN).
- Basic UDI-DI (GMN) SHALL NOT be used for supply chain identification or transactional purposes (e.g., labels, orders, deliveries, payments). Only the UDI-DI (GTIN) SHALL be used in the supply chain.
- UDI-DI (GTIN) SHALL NOT be used as a replacement for Basic UDI-DI (GMN).
- In documentation, Basic UDI-DI (GMN) 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. Spaces are not permitted as characters in the Basic UDI-DI (GMN).
- For construction industry, the following apply:
 - The Global Model Number may be processed as stand-alone information where applicable or with a GTIN on the same item. See sections <u>2.1.7</u> and <u>4.15</u> for the use of the GMN together with GTIN.

Attributes

Not applicable

Data carrier specification

 GMN is a $\mathsf{GS1}$ identification key not intended for use in a data carrier except for the construction industry.

Carrier choices

For the construction industry the following carrier choices apply:

- GS1 DataMatrix
- GS1 QR Code
- EPC/RFID (within user memory only)

Note: If the item is also scanned as a retail trade item a barcode that conforms to retail specifications is required.

Note: For regulated healthcare medical devices, the Basic UDI-DI (GMN) SHALL NOT be used in any labelling, physical marking, or GS1 AIDC data carrier on trade items associated with the Basic UDI-DI (GMN). The GMN MAY be included on documents or certificates, and in that case the rules for data content, format and data title in <u>3.9.13</u> apply.

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

See section <u>5.12.3.4</u>, GS1 symbol specification table 4.

Symbol placement

Not applicable

Unique application processing requirements

For a description of processing requirements, see section 7.

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Figure 3.9.12-1. Format of the element string

	GS1 Application Identifier	Software version		
8012	X_1 — variable length — X ₂₀			

The data transmitted by the barcode reader means that the element string denoting a software version has been captured. As this element string is an attribute of a software trade item, it must be processed with the GTIN of the software to which it is related (see section <u>4.13</u> Data relationships). When indicating this element string in the non-HRI text section of a label, the following data title SHOULD be used: **VERSION**

3.9.13 Global Model Number (GMN): AI (8013)

The GS1 Application Identifier (8013) indicates that the GS1 Application Identifier data field contains a GMN (Global Model Number). The GMN is used for the unique identification of a product model-or product family.

Note: This element string SHALL never be used to identify the entity as a trade item.

The GS1 Company Prefix (see section <u>1.4.4</u>) is allocated by GS1 Member Organisations to the brand owner that allocates the GMN. It makes the number unique worldwide. For product model or product family other than regulated healthcare medical devices, the GMN can be used in any labelling.

The structure and content of the model reference is 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.

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 Application Identifier	Global Model Number (GMN)					
		GS1 Cor	npany Prefix	< >	Model reference		Check characters
	8013	N ₁	Ni	$X_{i+1} \ \ldots$	variable length	X _{j (j<=23)}	$X_{j+1} \ X_{j+2}$

When indicating this element string in the non-HRI text section, the following data title SHOULD be used: ${\bf GMN}$

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 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.

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