WR #	GSCN Name	Effective Date
WR 24-040	Clarify GMN for Healthcare applications	Mar 2024

1 **Associated Work Request (WR) Number:**

2 **Background:**

Recent updates to GMN have made it less clear on how a GMN is NOT to be encoded in a data carrier. This GSCN is intended to clearly state the rule.

3 **Disclaimer**

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., medical device ~~product~~ family, apparel style, consumer electronics model) based on attributes common to the model 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 derived. 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 , SHALL NOT be reissued to another product model. The GMN SHALL NOT be used to identify a trade item. 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.

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.

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 2.1.7 and 4.15 for the use of the GMN together with GTIN.

Attributes

Not applicable

Data carrier specification

GMN is a GS1 identification key not intended for use in a data carrier except for the construction industry.

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 3.9.13 apply.

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 3.9.13 apply.~~

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

See section 5.12.3.4, GS1 symbol specification table 4.

Symbol placement

Not applicable

Unique application processing requirements

For a description of processing requirements, see section 7.