

General Specifications Change Notification (GSCN)

WR #	GSCN Name	Ratification Date
23-070	Groups of related trade items	Oct 2023

Associated Work Request (WR) Number:

These changes are to clarify language/tools in the General Specifications that can be used to help parties identify groups of related trade items. These items are those trade items that require a different GTIN but have similar attributes that make it reasonable to associate them as a product model.

Background:

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2.6.13 Global Model Number (GMN)

Application description

The GS1 Global Model Number (GMN) is the GS1 identification key <u>that may be</u> used to identify a product model <u>(e.g., or-medical device</u> product family, <u>apparel style</u>, <u>consumer electronic model</u>) based on attributes common to the model <u>or family</u> as defined by <u>the brand owner in accordance</u> with industry <u>guidelines (where avaliable</u>) or regulation. The <u>A product model is the basis from</u> 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 or product family, SHALL NOT be reissued to another <u>product model</u>. 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, physical marking, or GS1 AIDC data carrier on associated trade items.

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 Coi	mpany Prefi	× →	Model reference	>	Check characters
	8013	N1	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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4.9 GSIN rules

4.9.1 Allocating Global Shipment Identification Numbers

4.9.1.1 General rule

An individual Global Shipment Identification Number (GSIN) is a unique number, which remains the same for the life of the grouping of logistics or transport units to which it is assigned. When assigning a GSIN, the rule is that an individual GSIN number must not be reallocated within ten years of the shipment date from the seller or third party logistics provider (sender) of the GSIN to a trading partner buyer (recipient) to comply with the regulations of the World Customs Organisation (WCO). For goods that circulate within one country (domestic transport), the period of reuse is based on either governmental, industry or the discretion of the seller (sender) of the goods.

4.10 GCN rules

4.10.1 Allocating Global Coupon Numbers

The exact method used to allocate the Global Coupon Number (GCN) is left to the discretion of the issuing organisation. However, the GCN must remain unique for a period well beyond the lifetime of the records relevant to the coupon. For ease of administration, GS1 recommends that GCNs be allocated sequentially and not contain classifying elements.

4.11 CPID rules

4.11.1 Allocating Component/Part Identifiers

The exact method used to allocate the Component/Part Identifier (CPID) is left to the discretion of the issuing organisation.

4.12 GMN rules

4.12.1 Allocating Global Model Numbers

Global Model Numbers can be used to identify base product designs or specifications from which trade items are derived and/or registered. The exact method used to allocate the GMN is left to the discretion of the brand owner. However, each GMN must be unique for each product model or product family being identified and once assigned to one product model or product family. SHALL NOT be reissued to identify another product model or product family.

For regulated healthcare medical devices, the following applies:

Allocation of the Basic UDI-DI (GMN) is made per the discretion of the brand owner, but in compliance with regulatory rules.

4.12.1.1 Responsibility

The brand owner is responsible for the issuance and allocation of Global Model Numbers.

4.12.2 Information associated with Global Model Numbers

The data related to the product model or product family should <u>SHOULD</u> be recorded and shared using the Global Model Number as the key to the information. Examples of the type of information related to a GMN, may include the brand, certifications obtained, sewing pattern (e.g., in apparel sector), form / material/classification scheme (e.g., in construction sector), product line (e.g., in cosmetic sector). The following points highlight the relationship between GMN and GTIN:

All GMN level attributes are common for all GTINs associated with it.

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Additional attributes across all GTINs associated with one GMN may not be common.

If any attribute defined for a GMN changes in a way that trading partners are expected to distinguish the changed or new product model from previous/current product model, a new GMN must be assigned. Since all GMN attributes are common for all associated GTINs, this also implies the change of these GTINs according to guiding principle 1 of the <u>GS1 GTIN Management Standard</u> (see <u>https://www.gs1.org/1/gtinrules/en</u>).

For regulated healthcare medical devices, the following applies:

Basic UDI-DI attributes are common for all GTINs (UDI-DIs) associated with it. The identifier can be attributed to GTINs (UDI-DIs) associated with it, in the UDI database (e.g., EUDAMED).

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).

Figure 4.13.1-1. Invalid pairs of element strings

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.		

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