GSMP:
General Specifications Change Notification (GSCN)

WR #	GSCN Name	Effective Date
17-000103	**Basic Unique Device Identification – Device Identification (Basic UDI-DI)**	**6-Sep-2017**

Associated Work Request (WR) Number:

17-000103

Background:

With the approval by the European Parliament on 5 April 2017, new medical device regulations for both general and in-vitro diagnostic devices are helping to advance the unique device identification (UDI) system in Europe. A new standard is needed to enable the implementation of the Basic UDI-DI for medical device companies worldwide and, as a result, allow them to use GS1 standards for UDI in Europe. The design needs to include the flexibility to allow additional industry sectors to potentially leverage this solution in the future.

GS1 General Specification Change:

1.4.8 …

GS1 identification key type	Character set
Global Model Number	GS1 AI encodable character set 82

1.5 GS1 Company Prefix Allocation

…

A GS1 Company Prefix assigned to a member of any Member Organisation entitles that member to create any of the GS1 identification keys:

- …
- Global Model Number (GMN).

2.6.N Global Model Number (GMN)

Application description

A product model is a base product design or specification from which a trade item is derived. The trade item inherits major features / functions from the base model. The GS1 Global Model Number (GMN) is the GS1 Identification key used to identify product models from which trade items are derived. The GMN comprises the GS1 Company Prefix and a model reference. The model reference is alphanumeric and its structure is left to the discretion of the brand owner who assigns it.

This element string, once assigned to one product model, SHALL NOT be reissued to another. The GMN SHALL NOT be used to identify a Trade Item.

For regulated healthcare medical devices, the following applies:

When used for the unique identification of medical devices, the GMN's default, global data title SHALL be Basic UDI-DI or BUDI-DI. Other data titles which occur at local levels may be recorded in GS1 guidelines.

In regulated healthcare, the Basic UDI-DI (BUDI-DI) serves as the key element to allow the linkage of the different modules of the European Database for Medical Devices (EUDAMED). Per the EU Regulations, BUDI-DI is "The primary identifier of a device model. It is the DI assigned at the level of

the device unit of use[1]. It is the main key for records in the UDI database and is referenced in relevant certificates and EU declarations of conformity. (As defined by the European Medical Devices Regulation (EU MDR) and European *In-Vitro* Diagnostic Medical Devices Regulation (EU IVDR)."

[1] "device unit of use" pertains to the device "model" to be identified as stated in the previous sentence of the definition. It does not pertain to the term UoU DI (Unit of Use DI) or its UoU DI use on trade items.

By providing an identifier for the medical device model, the BUDI-DI will link medical device trade items identified by GTINs in the UDI database to pre-market, post-market activities (e.g., Device Registration, Certificates, Declaration of Conformity, Vigilance, Market Surveillance and Clinical Investigations).

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

- BUDI-DI (GMN) is used for medical device registration and is assigned independent of packaging / labeling and is different from the identifier for trade items in the supply chain (UDI-DI / GTIN.)
- All BUDI-DI level attributes (registration database) are common for all GTINs associated with it.
- All attributes across all GTINs associated with one BUDI-DI may not be common.
- BUDI-DI is used for device registration in the registration database. UDI-DI is used for trade item identification in the UDI database. UDI-DI and BUDI-DI 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 and BUDI-DI shall be made independent of one another.
- Brand owners are responsible for the assignment of BUDI-DI (GMN) and UDI-DI (GTIN.)

GS1 key

Definition

The Global Model Number is the GS1 identification key used to identify a product model. The key is comprises a GS1 Company Prefix and a model reference. The GMN must be processed in its entirety and not broken down into its constituent elements.

The Application Identifier to indicate the Global Model Number is AI (8013)

See section *0* for the list of all GS1 Application Identifiers.

Rules

See section 4, Application rules.

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

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 BUDI-DI and UDI-DI is 1:n (can be one to one or one to many), meaning a BUDI-DI can be related to more than one UDI-DI.

BUDI-DI (GMN) SHALL NOT be used for supply chain identification or transactional purposes (e.g., labels, orders, deliveries, payments) which SHALL be supported by UDI-DI (GTIN) in the supply chain.

UDI-DI (GTIN) SHALL NOT be used as a replacement for BUDI-DI (GMN).

In documentation, BUDI-DI 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 GS1 BUDI-DI identifier..

Attributes

Required

Not applicable

Optional

Not applicable

Rules

Not applicable

Data carrier specification

There are currently no data carrier specifications as the Global Model Number has only been approved for regulated healthcare identification of medical devices.

For medical devices, the BUDI-DI (GMN) SHALL NOT be used in any labelling, physical marking, or GS1 AIDC data carrier on trade items associated with the BUDI-DI. For this reason, there are no barcode specifications below and only Data Content, Format, and Data Title in Figure 3.2-1 apply.

Carrier choices

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

Not applicable

Symbol placement

Not applicable

Unique application processing requirements

Not applicable.

3.2 GS1 Application Identifiers in numerical order

Figure 0-1. GS1 Application Identifiers

AI	Data Content	Format (*)	FNC1 required (****)	Data title
8013	Global Model Number (GMN)	N4 +X..30	(FNC1)	GMN (for medical devices, the default, global data title is BUDI-DI)

3.3.N 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 product models.

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

The GS1 Company Prefix (see section *1.4.4*) is allocated by GS1 Member Organisations to the brand owner that allocates the GMN. It makes the number unique worldwide.

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**.

Figure 3.9.4-1. Format of the element string

Application Identifier	Global Model Number (GMN)	
	Global Company Prefix	Model Reference
8013	N_1 ... N_i	X_{i+1} ... variable length X_j (j<=30)

The data transmitted from the barcode reader means that the element string denoting a GMN has been captured. When indicating this element string in the non-HRI text section of a barcode label, the following data title SHOULD be used (see also section 3.2): **GMN**

Note: For medical devices, the GMN SHALL NOT be used in any labelling, physical marking, or GS1 AIDC data carrier on associated trade items. When indicating this element string in the non-HRI text on documents or certificates, the following data title SHOULD be used (see also section *0*): **BUDI-DI**

4.N 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 being identified and once assigned to one product model, SHALL NOT be reissued to identify another product model.

For regulated healthcare medical devices, the following applies:

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

4.N.1 Responsibility

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

4.N.2 Information associated with model numbers

The data related to the product model should be recorded and shared using the Global Model Number as the key to the information. Examples of the type of information held, may include the GMN of the brand owner and certifications obtained.

For regulated healthcare medical devices, the following applies:

BUDI-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.)

8.2 GS1 glossary of terms and definitions

The following glossary was updated for the Jan-2017 publication of this document. Please refer to the *www.gs1.org/glossary* for the latest version.

Term	Definition
BUDI-DI	The BUDI-DI is a unique identifier specific to a medical device product model and is represented by GS1's Global Model Number (GMN).
Global Model Number	The GS1 identification key used to identify a product model. The key comprises a GS1 Company Prefix and model reference.
model reference	A component of the Global Model Number (GMN) assigned by the brand owner to create a unique GMN.
product model	A base product design or specification from which a trade item is derived.
UDI	See Unique Device Identifier
UDI-DI	The UDI-DI is a unique identifier specific to a medical device trade item and is represented by a Global Trade Item Number (GTIN).
UDI-PI	The UDI-PI is a numeric or alphanumeric code that identifies the unit of device production. The different types of UDI-PIs include serial number, lot number, software identification and manufacturing or expiry date or both types of date.
Unique Device Identifier ('UDI')	The UDI is a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard. It allows the unambiguous identification of a specific medical device on the market. The UDI is comprised of the UDI-DI and the UDI-PI. The word 'Unique' does not imply serialisation of individual production units.
Unit of Use – DI	The Unit of Use DI serves to associate the use of a device with a patient in instances in which a UDI is not labelled on the individual device at the level of its actual use on a patient. For example, three clips (which do not carry a physical UDI marking themselves) are contained in a cartridge which is packaged inside a container, which does carry a labeled UDI.

152 **8.3 GS1 abbreviations**

Abbreviation	Term
BUDI-DI	Basic UDI - Device Identifier
GMN	Global Model Number
UDI	Unique Device Identifier
UDI-DI	Unique Device Identifier – Device Identifier
UDI-PI	Unique Device Identifier – Production Identifier
UoU DI	Unit of Use Device Identifier

153