WR #	GSCN Name	Effective Date
WR 24- 004	Medical device family definition	DD-MM-YYYY

Associated Work Request (WR) Number:

Background:

The term "medical device product family" is used in the General Specifications related to the Global Model Number use in healthcare. It is not, however, defined in the glossary. This work request seeks to align the General Specifications around commonly used terminology in the healthcare sector which is defined by an ISO standard.

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:

9 GS1 Standards glossary of terms

9.1 GS1 glossary of terms and definitions

The glossary lists the terms and definitions that are applied in this document. Please refer to the www.gs1.org/glossary for the online version.

Term	Definition
acceptance criteria	An allowance for a small measurement variation between commercial verifiers or operators during barcode verification testing.
add-on symbol	A barcode used to encode information supplementary to that in the main EAN/UPC barcode.
aggregated packaging (per EU 2018/574)	Any packaging containing more than one unit packet of tobacco products. For GS1, this may be either a trade item grouping or logistics unit.
AIDC media	The specific form of object/entity where a GS1 AIDC data carrier is displayed.
AIDC media type	The code list for objects/entities (e.g., patient wristband or staff ID card) that displays or carries a GS1 AIDC data carrier.
AIDC media type value	A predefined two-digit numeric code list value used to signify the AIDC media type (e.g., ID = 10, patient wristband = 01).
AIM DotCode	A two-dimensional barcode symbology rendered by printing dots per the AIM DotCode Specification.
allocation	The association of an issued GS1 Prefix, GS1 Company Prefix, or GS1 identification key to its corresponding entity or object in accordance with the GS1 rules and policies.
alphanumeric	A character set that contains alphabetic characters (letters), numeric digits (numbers) and other characters, such as punctuation marks.
aperture	A physical opening that is part of the optical path in a device such as a scanner, photometer, or camera. Most apertures are circular, but they may be rectangular or elliptical.
Application Standard Profile	A template that records conformance requirements of existing and any future AIDC application standards, the normative decisions (MSWG, ISO, Regulation, …), maintains centralisation of cross-application rules and related technical specifications.
asset type	A component of the Global Returnable Asset Identifier (GRAI), assigned by the asset owner or manager, in order to create a unique GRAI.
attribute	Additional information about an entity identified with a GS1 identification key.
autodiscrimination	The capability of a reader to automatically recognise and decode multiple barcode symbologies.
automatic identification and data capture (AIDC)	A technology used to automatically capture data. AIDC technologies include barcodes, smart cards, biometrics and RFID.
auxiliary patterns	Components of the EAN/UPC symbology. The centre guard bar pattern, the left guard bar pattern and the right guard bar pattern are examples of these.
bar gain/loss	The increase/decrease in bar width due to effects of the reproduction and printing processes.
barcode	A symbol that encodes data into a machine readable pattern of adjacent, varying width, parallel, rectangular or square dark and light spaces. The term barcode is inclusive of all linear and two-dimensional (2D) versions.
barcode verification	The assessment of the printed quality of a barcode based on ISO/IEC standards using ISO/IEC compliant barcode verifiers.
base unit	In a hierarchy of trade item groupings, the consumer trade item level or unit of use.
Basic Unique Device Identifier – Device Identifier (Basic UDI-DI)	The Basic UDI - DI is a unique identifier specific to a medical device product family. It is represented by GS1's Global Model Number (GMN).
batch/lot	Associates an item with information the manufacturer considers relevant for traceability of the trade item.
bearer bars	Bar abutting the tops and bottoms of the bars in a barcode or a frame surrounding the entire symbol, intended to equalise the pressure exerted by the printing plate over the entire surface of the symbol and/or to prevent a partial scan by the barcode reader.
brand owner	The organisation that owns the specifications of a trade item, regardless of where and by whom it is manufactured. The brand owner is normally responsible for the management of the Global Trade Item Number (GTIN).

Term	Definition
indirect mode	Mobile device information retrieval function when the code contains an identifier, which needs to be resolved to obtain the content or service. Resolving an identifier means looking it up, typically at a network service, to determine the corresponding content or service.
individual asset	An object that is part of the inventory of assets for a given company. (See also returnable asset.)
individual asset reference	A component of the Global Individual Asset Identifier (GIAI) assigned by the asset owner or manager to create a unique GIAI.
individual provider	Any person who provides or is a potential provider of a health care service to a subject of care.
Interleaved 2-of-5 symbology	Barcode symbology used for the ITF-14 barcode.
inverse exponent	The GS1 Application Identifier digit that denotes the implied decimal point position in an element string.
issuance	The generation of a GS1 Prefix, GS1 Company Prefix, or GS1 identification key in accordance with GS1 rules and policies by GS1 or a GS1 Member Organisation.
item reference	A component of the Global Trade Item Number (GTIN) assigned by the brand owner to create a unique GTIN.
ITF-14 barcode	ITF-14 (a subset of Interleaved 2-of-5) barcodes carry GTINs only on trade items that are not expected to pass through the point-of-sale.
kit	A collection of different regulated healthcare items assembled for use in a single therapy.
leading zero(es)	Adding zeroes in the leftmost position(s) of a data string when GTIN-8, GTIN-12, or GTIN-13 are encoded in an GS1 AIDC data carrier, message, or database that requires 14-digits or when used for the same intent in other data structures such as GRAI.
levels of AIDC marking	A graduated system of AIDC marking. The graduated system is defined as minimum, enhanced and highest levels of AIDC marking.
linear barcode	Barcode symbology using bars and spaces in one dimension.
local assigned code (LAC)	A particular use of the UPC-E barcode for restricted distribution.
location reference	A component of a Global Location Number (GLN) that allows the party defining the party or location to create a unique GLN.
logistic measures	Measures indicating the outside dimensions, total weight, or volume inclusive of packing material of a logistic unit. Also known as gross measures.
logistic unit	An item of any composition established for transport and/or storage that needs to be managed through the supply chain. It is identified with a Serial Shipping Container Code (SSCC).
main symbol	The barcode containing the identification number of the item (e.g., GTIN, SSCC). Used to determine the placement of any additional barcode information.
measure verifier digit	A digit calculated from the measure field in a Restricted Circulation Number (RCN) that is used to check that the data has been correctly composed.
Medical device family	A group of medical devices manufactured by or for the same organization and have the same basic design and performance characteristics related to safety, intended use and function.* *SOURCE: ISO 13485- Medical devices - Quality management systems – Requirements for regulatory purposes.
merchant	The party that makes a trade item available for sale. A retailer is one type of merchant. An online seller is another type of merchant.
model reference	A component of the Global Model Number (GMN) assigned by the brand owner to create a unique GMN.
module	The narrowest nominal width unit of measure in a barcode. In certain symbologies, element widths may be specified as multiples of one module. The nominal width (& height for 2D barcodes) of a single module is equivalent to the X-dimension.
modulo 10	The name of the algorithm – a simple checksum formula in the public domain – used to create a check digit for those GS1 identification keys that require one.
multiple unit blister/package	Immediate package for a medicine with more than one single unit. Package which fully encloses the pill/caplet/capsule. Each dosage form may be individually packaged. The individually blistered dosage forms are attached to each other in one strip.