GSMP:
General Specifications Change Notification (GSCN)

The Global Language of Business

WR #	GSCN Name	Effective Date
19-012	GMN update	**5-May-2019**

Associated Work Request (WR) Number:

19-012

Background:

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GS1 General Specification Change:

The recommended changes are marked as revision marks or highlighted in blue, relative to GS1 General Specifications version 19.

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Overview of new and changed sections

1 Basics and principles of the GS1 system

1.4 The GS1 identification system

1.4.8 Character set

The GS1 identification system supports three character sets; the specific character set depends on the identification key type. The three character sets are:

1. digit characters ('0' to '9');
2. characters from the ISO/IEC 646 Table 1 – Unique graphic character allocations[1], referred to within this standard as GS1 AI encodable character set 82 (see figure *7.11-1*); and
3. digit characters ('0' to '9'), upper case alphabetic characters ('A' to 'Z'), and three special characters ('#', '-', and '/'), referred to within this standard as GS1 AI encodable character set 39 (see figure *7.11-2*).

Regardless of the identification key type, the GS1 Prefix and (if applicable) the GS1 Company Prefix within any identifier use only the digit characters. Some identification key types that have a serial component also support different character sets for the serial component than for the portion that precedes it.

Figure 1.4.8-1. Synopsis of GS1 identification keys

GS1 identification key type	Character set
Global Trade Item Number (GTIN)	Digit characters
Global Location Number (GLN)	Digit characters
Serial Shipping Container Code (SSCC)	Digit characters
Global Returnable Asset Identifier (GRAI)	Digit characters (before serial component) GS1 AI encodable character set 82 (serial component)
Global Individual Asset Identifier (GIAI)	GS1 AI encodable character set 82
Global Service Relation Number (GSRN)	Digit characters
Global Document Type Identifier (GDTI)	Digit characters (before serial component) GS1 AI encodable character set 82 (serial component)
Global Identification Number for Consignment (GINC)	GS1 AI encodable character set 82
Global Shipment Identification Number (GSIN)	Digit characters
Global Coupon Number (GCN)	Digit characters
Component/Part Identifier (CPID)	GS1 AI encodable character set 39
Global Model Number (GMN)	GS1 AI encodable character set 82

As every identifier in the GS1 Identification System is a string, even when it is composed only of digit characters, all characters including leading zeroes are significant.

[1] While the ISO/IEC 646:1991 specification is not publicly available, the 6th edition of ECMA-6 corresponds to it and is available at http://www.ecma-international.org/publications/files/ECMA-ST/Ecma-006.pdf

2 Application standards

2.6 Special applications

2.6.13 Global Model Number (GMN)

Application description

The GS1 Global Model Number (GMN) is the GS1 identification key used to identify a product model or product family based on attributes common to the model or family as defined by industry or regulation. The GMN comprises the GS1 Company Prefix, a model reference and optional 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. The GMN SHALL NOT be used to identify a trade item.

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 enable to 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 the 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 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 *4.13*. Furthermore:

- The GMN SHALL NOT be used as a replacement for the GTIN.
- The GTIN SHALL NOT be used as a replacement for the GMN.

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 Regulated Healthcare medical devices that fall under the EU regulations[2], the following additional rules apply to Basic UDI-DI (GMN) (see figure 3.9.13-3 for further details):

- a check character pair SHALL be included, (see section 7.9.5 for further details)
- the length SHALL not exceed 25 characters, including the two check characters.

Attributes

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 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 section 3.9.13 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.

[2] EU MDR 2017/745: *https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0745*
EU IVDR 2017/746: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0746

3 GS1 Application Identifier definitions

3.2 GS1 Application Identifiers in numerical order

Figure 3.2-1. GS1 Application Identifiers

AI	Data Content	Format (1)	FNC1 required (4)	Data title
8013	*Global Model Number (GMN)*	N4+X..30	(FNC1)	GMN

NOTES:

(1): The first position indicates the length (number of digits) of the GS1 Application Identifier. The following value refers to the format of the data content. The following convention is applied:

- n implied decimal point position
- N numeric digit
- X any character in figure *7.11-1*
- N3 3 numeric digits, predefined length
- N..3 up to 3 numeric digits
- X..3 up to 3 characters in figure *7.11-1*

(4): All GS1 element strings that begin with GS1 Application Identifiers not contained in the predefined table shown in figure *7.8.4-2* SHALL be separated by a separator character unless this element string is the last one to be encoded in the symbol. For details on the separator character see section *7.8.3*.

3.9 GS1 Application Identifiers starting with digit 8

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 *1.4.4*) 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 optional 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 30 characters.

Figure 3.9.13-1. Format of the element string

GS1 Application Identifier	Global Model Number (GMN)				
	GS1 Company Prefix →		Model reference and optional check characters →		
8 0 1 3	N_1 ...	N_i	X_{i+1} ...	variable length	$X_{j\ (j<=30)}$

When indicating this element string in the non-HRI text section, the following data title SHOULD be used: **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), the total maximum length SHALL be 25 characters, including the mandatory check character pair. See figure 3.9.13-3.

Figure 3.9.13-2. Format of Basic UDI-DI (GMN) per EU regulations

	Global Model Number (GMN)					
	GS1 Company Prefix →		Model reference →			Check characters
	N_1 ...	N_i	X_{i+1} ...	variable length	$X_{j\ (j<=234)}$	X_{j+1} X_{j+2}

4 Application rules and management practices

4.13 GMN rules

4.13.1 Allocating Global Model Numbers

Global Model Numbers (GMNs) 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.

4.13.1.1 Responsibility

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

4.13.2 Information associated with Global Model Number

The data related to the product model or product family should be recorded and shared using the Global Model Number as the key to the information.

For regulated healthcare medical devices, the following applies:

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

7 AIDC validation rules

7.9 Check digit / character calculations

7.9.5 Check character calculation (for alphanumeric keys) -- NEW SECTION

GS1's check character algorithm uses MOD 1021,32 to calculate the check character pair for use in alphanumeric data structures (GS1 AI encodable character set, see table 7.11-1). The check character pair utilizes uppercase alpha and numeric characters (see table 7.9.5-2 Check character reference values). The check character set reduces potential keying errors by removing 0, O and 1, I (similar looking numeric alpha characters) from the possible results. The check character pairing also becomes more readily recognised due to the uppercase alpha numeric character structure. The check character pair enables the detection of various keying and encoding errors, including but not limited to:

- Character substitution(s)
- Character transposition(s)
- Logical shifts
- Character addition(s)
- Character omission(s)

Check character calculation steps:

- **Calculation step 1:** For each character, retrieve the assigned reference value from figure 7.9.5-1
- **Calculation step 2:** Each symbol character position is given a prime number weight. Beginning with the right most non-check character (X_j) and progressing left to first character (N_1) the prime weight increases 2, 3, 5, 7, 11, 13, to n; "n" denotes the number of characters representing data not including the check character pair.
- **Calculation step 3:** Multiply each assigned reference value (from step 1) by the weight (from step 2).
- **Calculation step 4:** Total the results of the calculations in step 3.
- **Calculation step 5:** Perform a MOD **1021** on the sum of the products (step 4).
- **Calculation step 6:** The result of step 5 is the check character's reference value.
- **Calculation step 7:** Based on the check character's reference value (Ck), determine the GMN check character using the following:
  a. Ck = C1 * 32 + C2, (C1, C2 are the assigned reference values for table 7.9.5-2)
     i. C1 = INT (Ck / 32), (the whole number to the left of the decimal)
     ii. C2 = Ck MOD 32
  b. Retrieve the alphanumeric characters for X_{j+1} and X_{j+2} using C1 and C2

Figure 7.9.5-1. GS1 AI encodable character reference values

Character Set	Assigned Value		Character Set	Assigned Value		Character Set	Assigned Value
!	0		B	30		e	60
"	1		C	31		f	61
%	2		D	32		g	62
&	3		E	33		h	63

Character Set	Assigned Value		Character Set	Assigned Value		Character Set	Assigned Value
'	4		F	34		i	64
(	5		G	35		j	65
)	6		H	36		k	66
*	7		I	37		l	67
+	8		J	38		m	68
,	9		K	39		n	69
-	10		L	40		o	70
.	11		M	41		p	71
/	12		N	42		q	72
0	13		O	43		r	73
1	14		P	44		s	74
2	15		Q	45		t	75
3	16		R	46		u	76
4	17		S	47		v	77
5	18		T	48		w	78
6	19		U	49		x	79
7	20		V	50		y	80
8	21		W	51		z	81
9	22		X	52			
:	23		Y	53			
;	24		Z	54			
<	25		_	55			
=	26		a	56			
>	27		b	57			
?	28		c	58			
A	29		d	59			

Figure 7.9.5-2. Check character reference values

Character Set	Assigned Value		Character Set	Assigned Value		Character Set	Assigned Value
2	0		D	11		Q	22
3	1		E	12		R	23
4	2		F	13		S	24
5	3		G	14		T	25
6	4		H	15		U	26
7	5		J	16		V	27
8	6		K	17		W	28
9	7		L	18		X	29
A	8		M	19		Y	30
B	9		N	20		Z	31

Character Set	Assigned Value		Character Set	Assigned Value		Character Set	Assigned Value
C	10		P	21			

Figure 7.9.5-3. Example of a check character calculation (based on 25 character Global Model Number)

Position	P_1	P_2	P_3	P_4	P_5	P_6	P_7	P_8	P_9	P_{10}	P_{11}	P_{12}	P_{13}	P_{14}
GMN	1	9	8	7	6	5	4	A	d	4	X	4	b	L
Assigned Value	14	22	21	20	19	18	17	29	59	17	52	17	57	40
Multiply by Weight	X 83	X 79	X 73	X 71	X 67	X 61	X 59	X 53	X 47	X 43	X 41	X 37	X 31	X 29
Results to Sum	1162	1738	1533	1420	1273	1098	1003	1537	2773	731	2132	629	1767	1160

	Example of a check character calculation for 25-character GMN continued										
Position	P_{15}	P_{16}	P_{17}	P_{18}	P_{19}	P_{20}	P_{21}	P_{22}	P_{23}	P_{24}	P_{25}
GMN	5	t	t	r	2	3	1	0	c	**2**	**K**
Assigned Value	18	75	75	73	15	16	14	13	58		
Multiply by Weight	X 23	X 19	X 17	X 13	X 11	X 7	X 5	X 3	X 2		
Results to Sum	414	1425	1275	949	165	112	70	39	116		

Summary totals	
Sum weighted assigned values	24521
MOD **1021** for the Sum weighted assigned values	17
Integer Results of MOD **1021** Sum weighted assigned values divided by 32	**0**
Remainder of MOD **1021** Sum weighted assigned values multiplied by 32	**17**
Check character for position P_{24} referenced from table 7.9.5-2	**2**
Check character for position P_{25} referenced from table 7.9.5-2	**K**

8 GS1 Standards glossary of terms

8.1 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
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).
Global Model Number (GMN)	The GS1 identification key used to identify a product model or product family. 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.
check character pair	A final character pair calculated from the other characters of some GS1 identification keys. These characters are used to check that the data has been correctly composed.
GS1 check character calculation	An algorithm used by the GS1 system for the calculation of the check characters to verify accuracy of data.

8.2 GS1 abbreviations

Abbreviation	Term
GMN	Global Model Number