

GS1 Standards in Healthcare Manual

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About GS1

GS1® is a neutral, not-for-profit, global organization that develops and maintains the most widely-used supply chain standards system in the world. GS1 Standards improve the efficiency, safety, and visibility of supply chains across multiple sectors. With local Member Organizations in over 112 countries, GS1 engages with communities of trading partners, industry organizations, governments, and technology providers to understand and respond to their business needs through the adoption and implementation of global standards. GS1 is driven by over a million user companies, which execute more than six billion transactions daily in 150 countries using GS1 Standards.

About GS1 Belgium & Luxembourg

GS1 Belgium & Luxembourg, a member of GS1 global, is a not-for-profit information standards organization that facilitates industry collaboration to improve supply chain visibility and efficiency through the use of GS1 Standards, the most widely used supply chain standards system in the world. Nearly 6.000 businesses in several industries rely on GS1 Belgium & Luxembourg for trading-partner collaboration that optimizes their supply chains, drives cost performance and revenue growth while also enabling regulatory compliance. They achieve these benefits through solutions based on GS1 global unique numbering and identification systems, barcodes, data synchronization, and electronic information exchange.

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Preface

Companies and other health organizations will find in this user-friendly manual an introduction to the international GS1 Standards and Solutions. This document will not go into detail and does not replace the standard reference document: the '[GS1 General Specifications](#)'.

Please note that national or international regulations prevail over this manual. The use of this manual is purely informative. This manual aims at helping users to implement the GS1 system of standards.

The barcodes reproduced in this manual are examples and cannot be used as reference.

The GS1 General Specifications Document is available in English on the GS1 Global Website (www.gs1.org). GS1 Belgium & Luxembourg also offer numerous publications in English, Dutch and French that address particular aspects of those general specifications.

For more information, please consult our website (www.gs1belu.org).

For more information:



Rue Royale/Koningsstraat 76 B-1
BE-1000 Bruxelles/Brussel

T +32 (0) 2 229 18 80

E info@gs1belu.org

W www.gs1belu.org

Our helpdesk:

Barcodes@gs1belu.org

1 Introduction

Global standards for automatic identification, data capturing and sharing provide an opportunity to make the healthcare supply chain safer as well as more efficient and accurate. Healthcare regulators and trading partners have realised that a global standardised identification system from manufacturer to patient treatment is imperative to comply with the increasing need for product traceability around the world.

The GS1 System, globally endorsed by the healthcare community, is the most widely used identification system worldwide with more than 6 billion transactions per day. Built on a foundation of identification keys (such as the Global Trade Item Number) and attributes (such as a batch/lot number, expiry date, unique serial number, ...), it is uniquely suited to meet the needs of the healthcare industry. Data sharing amongst trading partners and regulators significantly increases patient safety, as data quality rises.

Healthcare systems around the globe are facing challenges that affect the entire supply chain, from manufacturers to wholesalers, distributors, group purchasing organisations and healthcare providers. Everyone is concerned primarily with two main issues: **increasing supply chain efficiency** and, more importantly, **ensuring patient safety**. The regulatory landscape continues to evolve; new regulations will have a direct impact on the Healthcare supply chain, requiring stakeholders to implement automatic identification technologies, electronic product catalogues, serialisation (a unique serial number on each package or product, where appropriate) and/or traceability systems.

Supply chain data standards can provide a global framework for all stakeholders to comply with regulatory and tender requirements and to meet the challenges of today's complex Healthcare supply chain.

The GS1 System of Standards is a flexible architecture that ensures maximum efficiency. It is built around and upon several elements:

- **GS1 Identification Keys** are the foundation of the GS1 System and ensure the globally unique identification of products, locations, assets, etc.
- **GS1 Application Identifiers** present a standardised way to encode additional information, such as expiry date, lot number and serial number.
- **GS1 Barcodes** provide a portfolio of data carriers including several linear barcodes and two dimensional barcodes.
- **GS1 EDI** enables Electronic Data Interchange, providing clear guidelines for creating electronic versions of all sorts of business documents in the Order to Cash cycle.
- **GS1 Global Data Synchronisation Network (GDSN)** allows users to obtain, maintain, validate and exchange master data in a secure and reliable environment via a network of GDSN-certified data pools.

65 regulatory agencies worldwide accept the use of GS1 standards in Healthcare.

2 Identification

2.1 Identification of Trade Items

The GTIN is used to uniquely identify trade items on global level.

Definition

A Global Trade Item Number (GTIN) is used to identify any item (trade item or service) upon which there is a need to retrieve pre-defined information and that may be priced, ordered or invoiced at any point in any supply chain.

GTINs are assigned by the brand owner of the product, and are used to identify products as they move through the global supply chain to the hospital or ultimate end user.

The GTIN uniquely identifies a product at each packaging level.
For example:

- A box of 150 Brand X of latex gloves
- A carton of 6 boxes of Brand X of latex gloves

Use of GTIN-13 or GTIN-14:

GTIN-13	5412150000154	GTIN-13	5412150000161	GTIN-13	5412150000178
		GTIN-14	15412150000151	GTIN-14	25412150000158



Item



Case



Pallet

GTINs can be assigned as 8 digits, 12 digits (U.S. standard only), 13 digits, or 14 digits in length (known as GTIN-8, GTIN-12, GTIN-13 and GTIN-14, respectively).

However, within the EU medical supply chain, the GTIN-13 and GTIN-14 are predominantly used.

The choice of format is often related to point-of-sale. The most widely used practices are to:

- Assign a GTIN-13 to medical products to be sold at retail
- Assign a GTIN-14 to medical products that will not be sold at retail

Although these practices are the **most prevalent**, they are **not required**. For example, GTIN-13 is also acceptable in non-retail environments, and the use of GTIN-14 is the most predominant format in global healthcare.

Consult the [GS1 General Specifications](#) for all of your options.

2.1.1 Products sold at Retail

Each GTIN-13 is a numerical string comprising three distinct segments:

- **GS1 Belgilux Company Prefix:** A globally-unique number assigned to a company/organization by GS1 Belgium & Luxembourg to serve as the foundation for generating GS1 Identification keys (e.g., GTIN). The GS1 Company Prefixes vary in length depending on the company/organization's needs.
- **Item Reference:** A number assigned by the holder of the GS1 Company Prefix to uniquely identify each trade item. The Item Reference varies in length as a function of the Company Prefix length.

- **Check Digit:** A one-digit number calculated from the first 12 digits of the GTIN-13 and used to ensure data integrity.

Although the length of the GS1 Belgilux Company Prefix and the length of the Item Reference vary, they will always be a combined total of 12 digits in a GTIN-13. The addition of the Check Digit completes the 13 digits of the GTIN-13.

GTIN-13 structure:

GS1 Belgilux Company Prefix (54 M ₁ M ₂ ...) and Item Reference (X ₁ X ₂ ...)												Check Digit
5	4	M ₁	M ₂	M ₃	M ₄	M ₅	X ₁	X ₂	X ₃	X ₄	X ₅	C
5	4	M ₁	M ₂	M ₃	M ₄	M ₅	M ₆	X ₁	X ₂	X ₃	X ₄	C
5	4	M ₁	M ₂	M ₃	M ₄	M ₅	M ₆	M ₇	X ₁	X ₂	X ₃	C
5	4	M ₁	M ₂	M ₃	M ₄	M ₅	M ₆	M ₇	M ₈	X ₁	X ₂	C

The use of a GTIN-13 can also be used for all hierarchical levels. Nevertheless, GS1 recommends the use of a GTIN-14, for all products not sold at retail point-of-sale.

Use of GTIN-13 for all hierarchical levels:

GTIN-13	GTIN-13	GTIN-13	GTIN-13
541234500013	5412345000433	5412345000693	5412345000259
			

2.2 Identification of Product Groupings

A GTIN-14 is used for Products not sold in retail or for groupings of product.

Each GTIN-14 is a numerical string comprising four distinct segments. The four segments in a GTIN-14 are:

- **Indicator Digit:** The indicator digit identifies packaging level. The field consists of a numeric value from 1 to 8.
(The number "0" is used in this position as a fill character when a GTIN-13 is represented in 14-digit format.)
- **GS1 Belgilux Company Prefix:** A globally unique number assigned to a company by GS1 Belgium & Luxembourg to serve as the foundation for generating GS1 Identification keys.
- **Item Reference:** A number assigned by the holder of the GS1 Company Prefix to uniquely identify a trade item.
- **Check Digit:** A one-digit number calculated from the first 13 digits of the GTIN-14 used to ensure data integrity.

The GTIN-14 will always be composed of 12 digits (company prefix + item reference), preceded by the indicator digit and ended by the check-digit.

GTIN-14 Structure:

Indicator	GS1 Belgilux Company Prefix (54 M ₁ M ₂ ...) and Item Reference (X ₁ X ₂ ...)												Check Digit
1-8	5	4	M ₁	M ₂	M ₃	M ₄	M ₅	X ₁	X ₂	X ₃	X ₄	X ₅	C
	5	4	M ₁	M ₂	M ₃	M ₄	M ₅	M ₆	X ₁	X ₂	X ₃	X ₄	C
	5	4	M ₁	M ₂	M ₃	M ₄	M ₅	M ₆	M ₇	X ₁	X ₂	X ₃	C
	5	4	M ₁	M ₂	M ₃	M ₄	M ₅	M ₆	M ₇	M ₈	X ₁	X ₂	C

2.3 Identification of Locations

The Global Location Number (GLN) makes possible the unique and unambiguous identification of physical locations or legal entities. The GLN uses a similar data structure as the GTIN-13 data structure and the numbers are non-significant. The same digits can be used for GTIN-13 and a GLN. No confusion arises because the applications are totally separate.

Each GLN is a numerical string comprising three distinct segments:

- **GS1 Belgilux Company Prefix:** A globally unique number assigned to a company by GS1 Belgium & Luxembourg to serve as the foundation for generating GS1 Identification keys.
- **Location Reference:** A number assigned by the holder of the GS1 Company Prefix to uniquely identify a location.
- **Check Digit:** A one-digit number calculated from the first 12 digits of the GLN used to ensure data integrity.

GLN Structure:

GS1 Belgilux Company Prefix (54 M ₁ M ₂ ...) and Location Reference (L ₁ L ₂ ...)												Check Digit
5	4	M ₁	M ₂	M ₃	M ₄	M ₅	L ₁	L ₂	L ₃	L ₄	L ₅	C
5	4	M ₁	M ₂	M ₃	M ₄	M ₅	M ₆	L ₁	L ₂	L ₃	L ₄	C
5	4	M ₁	M ₂	M ₃	M ₄	M ₅	M ₆	M ₇	L ₁	L ₂	L ₃	C
5	4	M ₁	M ₂	M ₃	M ₄	M ₅	M ₆	M ₇	M ₈	L ₁	L ₂	C

3 The GS1 Application Identifiers

In addition to the GTIN, there may be certain item-specific information that manufacturers or supply chain partners want marked on products to enable communication of that information wherever the barcode is scanned.

The GS1 System provides "Application Identifiers" to support this need.

GS1 Application Identifiers (AIs) are a finite set of specialized Identification keys encoded within barcodes to indicate the type of data represented in the various barcode segments. Each data element in a barcode is preceded by its AI.

Each AI is a two, three, or four digit numeric code. When rendered in human-readable form, the AI is shown between parentheses. However, the parentheses are not part of the barcode's encoded data. GS1 AIs are standard throughout the world and are familiar to IT system developers. GS1-128, GS1 DataMatrix can all carry AIs, and more than one AI can be carried in one barcode.

Extract of the full list of Application Identifiers:

AI	Description	Format
01	Global Trade Item Number	N2+N14
10	Batch/Lot Number	N2+AN...20
11	Production/Manufacturing Date - YYMMDD	N2+N6
17	Expiration Date - YYMMDD	N2+N6
21	Serial Number	N2+AN...20
8017	Global Service Relationship Number - Provider	N4+N18
8018	Global Service Relationship Number - Recipient	N4+N18

Legend:

- N:** Numerical
- AN:** Alphanumeric
- ..:** Variable length

When encoding a barcode, each data element in the barcode is preceded by its AI. The AI defines data type and field size.

For example:

- AI for GTIN is (01). Thus, when "(01)" appears in the numerical string, it means that a GTIN follows in the next segment with a fixed length of 14 digits.
- AI for expiration date is (17). When "(17)" appears in the numerical string, it means that an expiration date follows in the next segment, with a fixed length of 6 digits.

3.1 Most widely used Application Identifiers in Healthcare

In Healthcare, some Application Identifiers are mandated by regulators. Therefore, a selection of the most widely used AIs in Healthcare has been made for this manual.

For a complete list of AIs, please consult our [GS1 General Specifications](#).

The data elements within a barcode are separated (or delimited) through the use of GS1 Application Identifiers (AIs).

The AI's that are relevant to this guideline are:

- AI (01) GTIN
- AI (10) Batch/Lot Number
- AI (11) Production/manufacturing Date
- AI (17) Expiration Date
- AI (21) Serial Number

3.1.1 AI (01) – GTIN

The Application Identifier (01) indicates that the GS1 Application Identifier data field contains a GTIN. The GTIN may be a GTIN-8, GTIN-12, GTIN-13 or a GTIN-14.

AI (01) has a fixed length of 14 digits. To encode a GTIN-8, GTIN-12 or GTIN-13 within Application Identifier GTIN - (01), use filler digit(s) "0" before your GTIN.



(01)05412345000013

Data Carrier: 2D GS1 DataMatrix

Content: GTIN-13, with filler digit 0

3.1.2 AI (10) – Batch/Lot Number

A Batch/Lot Number is typically assigned at the point of manufacturer using a production lot number or a time or an internal production code. Batch/Lot Number is represented by Application Identifier (10). The data is alphanumeric and the length is variable with a maximum of 20 alphanumeric characters.



(01) 0 0614141 99999 6 (10) 10ABCDEF123456

Data Carrier: 1D GS1-128

Content: GTIN-12, with 2 filler digits "0" and Batch/Lot Number

3.1.3 AI (11) - Production/Manufacturing Date

Manufacturing Date can also be referred to as production date. It indicates the production or assembly date determined by the manufacturer. Manufacturing/Production Date is represented by Application Identifier (11). The data is numeric and the length is fixed at six numeric characters with the structure YYMMDD.



(01)15412345601255

(11)160924

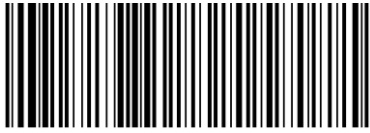
(10)ABC123

Data Carrier: 2D GS1 DataMatrix

Content: GTIN-14, Production Date and Batch/Lot Number

3.1.4 AI (17) – Expiration Date

Expiration Date is often referred as expiry date or maximum durability date. It indicates the limit of consumption or use of a product. Expiration Date is represented by Application Identifier (17). The data is numeric and the length is fixed at six numeric characters with the structure YYMMDD.



(01) 0 5412345 00060 0 (17) 201025

Data Carrier: 1D GS1-128

Content: GTIN-13 with filler digit "0", Expiration Date

3.1.5 AI (21) – Serial Number

Serial Number is represented by Application Identifier (21). The data is alphanumeric and the length is variable with a maximum of 20 alphanumeric characters. The overall creation and structure of the Serial Number (e.g., random versus sequential, numeric versus alphanumeric; etc.) is determined by the manufacturer.



(01) 1 5412345 00012 6
(17) 201122
(10) ABC123
(21) 0001

Data Carrier: 2D GS1 DataMatrix

Content: GTIN-14, Expiration Date, Batch/Lot Number and Serial Number

4 GTIN Healthcare Allocation Rules

A Global Trade Item Number (GTIN) is used to identify any item (trade item or service) upon which there is a need to retrieve pre-defined information and that may be priced, ordered or invoiced.

A separate, unique GTIN is required **whenever any of the pre-defined characteristics of an item are different in any way that is relevant to the trading process.**

As a guiding principle, if the customer is expected to distinguish a new trade item from an old trade item and purchase accordingly, a new GTIN should be assigned to the new trade item. These rules are intended for global use.

Exceptions may occur only when local regulatory or legal requirements mandate otherwise. Any law or regulation that contradicts these rules shall supersede these rules.

Specific rules that apply to packaging and raw material trade items supplied to manufacturing companies can be found at www.gs1.org/gtinrules.

4.1 Definitions of Healthcare Items

4.1.1 Healthcare Trade Item

The legal definitions for healthcare items will differ from one country to another. Indeed some legal definitions for drugs are simply 'A substance recognised by an official legal entity'. This section therefore aims to provide a global overview.

4.1.2 Kit

Kits are collections of non-homogeneous, separable components that are identified, purchased, and supplied as a single trade item for a specific clinical or commercial purpose.

There are two primary types of kits:

1. **Finished product kit:** kits that are an assembly of only finished goods. Components are trade items, where each component is a trade item identified by a GTIN. Components do not need to be individually packaged; but are independently identified at the component packaging level (e.g. may be sellable, identified and available for trade).
2. **Manufactured kit:** kits that are completed or finished in the kitting process. At least one component of a manufactured kit is not a finished trade item and therefore is not identified with a GTIN.

4.1.3 Pharmaceuticals

Non-prescription

A non-prescription pharmaceutical product (also known as **Over the Counter**) is a drug or medicinal specialty whose dispensing or administration does not require medical authorisation. Normally it can be used by the consumers under their own initiative and responsibility to prevent, relieve or to treat symptoms or mild diseases. Its use, in the form, conditions, and authorised dosages should be safe for the consumer. This covers healthcare items that do not require a prescription or direct medical intervention.

Prescription

A Prescription (often referred to as a Pharmaceutical) Product is a drug or medicinal specialty that requires a prescription or direct medical intervention. Typical examples include, medicated bandages, pain medication, injectables, etc. and can normally only be obtained with a prescription from an appropriate health care practitioner.

Hospital Pharmacy Product

A Hospital Pharmacy Product is a product that has to be manufactured by a hospital pharmacy for internal or multi-hospital use, thus it is not (or is no more) marketed by pharmaceutical company that supplied the raw material. These products may correspond to the Prescription or Non-Prescription category. In any case, they have to be clearly identified from the production to the bedside.

4.1.4 Medical Devices

Medical device means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purposes of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury
- Investigation, replacement, modification, or support of the anatomy or of a physiological process
- Supporting or sustaining life
- Control of conception
- Sterilization of medical devices
- Providing information for medical purposes by means of in vitro examination of specimens derived from the human body and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

4.1.5 Branded Items

The Brand Owner, the organisation that owns the specifications of the trade item regardless of where and by whom it is manufactured, is responsible for the allocation of the Global Trade Item Number (GTIN). By joining a GS1 Member Organisation, the company receives a GS1 Company Prefix which is for the sole use of the company to which it is assigned. The GS1 Company Prefix may not be sold, leased, or given, in whole or in part, for use by any other company.

The company that owns the product and makes the Regulatory Filing is responsible for the GTIN Allocation. For healthcare items it is common for national regulators to require the submission of a product filing from a legal entity based within the jurisdiction of the regulator. Such arrangements have no direct impact on GTIN Allocation but need to be covered by the normal contractual arrangements.

The Brand Owner can only be responsible for GTIN Allocation until the item leaves their control. For example a complex medical device can be reconfigured. Individual customer configuration therefore cannot impact GTIN Allocation.

4.1.6 Kitter

The kitter is the Responsible Entity that defines the kit's contents, specifications and labelling. Within the EU, the kitter owns the CE mark. The kitter may or may not assemble the kits, and may engage a third party, or kit assembler, to produce the finished trade items.

4.2 Allocation of the Numbers

The guiding principle is if **any significant change** is made and it is expected to distinguish a new trade item from an old trade item and use accordingly, a new GTIN should be assigned.

4.2.1 Pre-defined Characteristics

Although this list is not exhaustive, the basic pre-defined characteristics of a trade item are:

- Product Name, Product Brand, and Product Description
- Formulation (active ingredients)
- Strength
- Dosage (or usage)
- Net quantity (weight, volume, or other dimension impacting trade)
- Packaging configuration
- Form, Fit or Function
- For groupings, the number of elementary items contained, and their subdivision in sub-packaging units, the nature of the grouping (carton, pallet, box-pallet, flat-pallet...)

A modification to any of the basic elements that characterise a trade item will usually lead to a change in the GTIN.

4.2.2 Lead time in re-use of a GTIN

Companies must ensure that GTINs allocated to Regulated Healthcare Trade Items shall never be reused.

Exception: Regulated Healthcare Trade Items that have been withdrawn from the market and are reintroduced may use the original GTIN if they are reintroduced without any modifications or changes which require a new GTIN as specified by the GTIN Allocation Rules.












5 Data Capturing

Manufacturers mark all of their products with the applicable GTIN so that they can be properly identified as they move through the supply chain. To this end, manufacturers encode the GTIN into GS1 data carriers, and then affix a data carrier to each product.

GS1 Data Carriers provide machine-readable representations of GS1 Identification Numbers that facilitate automatic identification and data capture. In addition to the symbol marking, most GS1 data carriers include a plain text version of the GTIN (human readable) as well to facilitate manual data entry when necessary.

In order to accommodate a variety of environments and applications, the GS1 System supports seven different barcodes. Some barcodes are only approved for retail applications. Some barcodes are only approved for non-retail applications. And some are approved for both. In addition, some GS1 Barcodes are able to carry production information (encoded with GS1 AIs) and others are not. This manual will only cover 4 of those barcodes.

Type of barcode per scanning environment:

The Warehouse	The Hospital	The Point-of-Care	The Retail POS
			
			
			
GTIN-13	GTIN-13	GTIN-13	GTIN-13
GTIN-14	GTIN-14	GTIN-14	

5.1 GTIN only

5.1.1 EAN-13



The EAN barcode can be read omnidirectionally. It must be used for all items that are scanned at the Point-of-Sale.

Sizes

Width

The width does not include the quiet zones

- Min.: 29.83 mm / Min. X-dimension¹: **0.264 mm**
- Nominal: 37.29 mm / Nominal X-dimension : **0.330 mm**
- Max.: 74.58 mm / Max. X-dimension: **0.660 mm**

Height

The larger the X-dimension, the higher the barcode should be:

- X-dimension of 0.264 mm: **18.28 mm**
- X-dimension of 0.330 mm: **22.85 mm**
- X-dimension of 0.660 mm: **45.70 mm**

Quiet Zones

- Left: **11 times** the X-dimension
- Right: **7 times** the X-dimension

A useful device to help maintain the Quiet Zones in some production processes is to include a "less than" (<) character in the human readable field aligned with the edge of the Quiet Zone. Those marks are referred to as the "Quiet Zone Indicators".

5.1.2 ITF-14



The use of the ITF-14 barcode is restricted to the barcoding of trade items NOT scanned at retail point-of-sale. This barcode is better suited for direct printing onto corrugated fibreboard.

Sizes

Width

Dimensions below do not include the bearer bar and quiet zones:

- Min.: 71.40 mm x / Min. X-dimension: **0.495 mm**
- Nominal: 142.75 mm / Nominal X-dimension : **0.495 mm**
- Max.: 142.50 mm / Max. X-dimension: **1.016 mm**

¹ width of the smallest bar in the barcode.

Height

- **31.75 mm**

Quiet Zones

- Left: **10 times** the X-dimension
- Right: **10 times** the X-dimension

5.2 GTIN and Production Identifiers

5.2.1 GS1-128



The GS1-128 barcode is not intended to be read on items scanned at the retail point-of-sale. The GS1-128 barcode can encode the GTIN and additional data using the GS1 Application Identifiers.

(01) 1 5424567 00012 9 (10) 10ABCEDF123456

The GS1-128 Barcode is not to be confused with CODE 128 which is not a GS1 barcode!

Sizes

Width

Outer cases:

- X-dimension range is from **0.495 mm** to **1.016 mm**

Medical Device:

- X-dimension range is from **0.250 mm** to **0.495 mm**

Height

Outer cases:

- Height of the bars must always be at least **32 mm**

Medical Device:

- Height of the bars must be at least **12.70 mm**

Quiet Zones

- Left: **10 times** the X-dimension
- Right: **10 times** the X-dimension

5.2.2 2D GS1 DataMatrix

The use of a GS1 DataMatrix has been endorsed by many Healthcare leaders as the barcode for Healthcare. New European Legislation mandate the use of such 2D Barcode.



(01)15415478940017
(10)ABC123

GS1 DataMatrix is a variant of Data Matrix ISO version ECC 200. The Function 1 Symbol Character in the first position ensures GS1 System compatibility. GS1 DataMatrix can encode the GTIN and additional data using the GS1 Application Identifiers.

It is currently being implemented for the barcoding on small medical / surgical instruments and healthcare items.

Sizes

Width and height

- Minimum x-dimension **0.396 mm**
- Nominal x-dimension: **0.495 mm**
- Maximum x-dimension: **0.990 mm**

Quiet Zones

- Left: **1 time** the X-dimension
- Right: **1 time** the X-dimension

For more technical information on the GS1 DataMatrix, please read the "[GS1 DataMatrix An introduction and technical overview of the most advances GS1 Application Identifiers compliant technology](#)".

6 Master Data Management

6.1 Global Data Synchronization Network

The Global Data Synchronization Network (GDSN) provides an efficient and effective approach to:

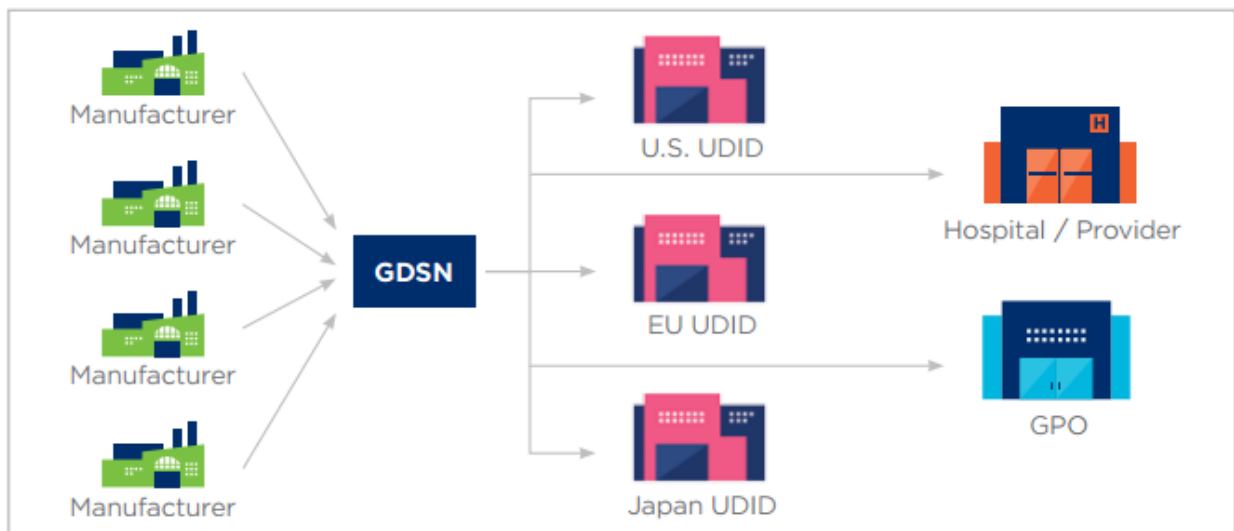
- Storing GS1 Identifiers with their associated attributes
- Checking to make sure that the Identification keys and attributes are properly defined and formatted
- Sharing that information with supply chain partners

The GDSN is a network of interoperable data pools connected by the GS1 Global Registry®. The GDSN-certified Data Pools store and manage supply chain information for their users, and the GS1 Global Registry connects those data pools together.

The GDSN offers a continuous, automated approach to data management that ensures that supply chain information is identical among trading partners, increasing data accuracy and driving costs out of the supply chain.

The use of GDSN allows manufacturers to only enter data once and publish to many recipients. GS1 Belgium & Luxembourg's GDSN Data pool is called the Central Data Bank (CDB), and is currently used by many local organizations.

GDSN network:



The use of GDSN has been endorsed by regulators to populate their local database, such as the Global Unique Device Identification Database (GUDID) of the U.S. FDA.

7 GS1 Standards in Action

7.1 Medical Devices – U.S. Unique Device Identification

The UDI Rule establishes a Unique Device Identification system for medical devices. Under the rule, the healthcare community and the public will be able to identify a device through a Unique Device Identifier (UDI) that will appear on the label and package of a device.

UDIs will be presented on device labels in both a human-readable format and a machine-readable format that can be read by automatic identification data capture technology. Also, re-usable devices that need to be "reprocessed" before reuse will also be directly marked with a UDI.

The UDI will provide a standardized way to identify medical devices across all information sources and systems, including electronic health records and devices registries. In addition, device labellers will submit device information to a new FDA database called the Global Unique Device Identification Database (GUDID).

The GUDID will provide critical information about medical devices, and the UDI will provide the key for obtaining device information from the GUDID.

7.1.1 UDI Segments

A UDI is a unique numeric or alphanumeric identification code assigned to medical devices by the labeller (e.g., manufacturer) of the device. This using the format specified and agreed upon during the FDA UDI Issuing Agency accreditation process.

A UDI includes two segments: a "device identifier" and a "production identifier"

UDI in GS1 standards:

UDI Unique Device Identification	GS1 standards Product Identification
DI Device Identifier (DI)	GTIN Global Trade Item Number
PI Production Identifier (PI) <i>if applicable</i> <i>Production Identifier data will vary by medical device type and manufacturer current practice.</i>	AI Application Identifier (AI) • Expiration date AI(17) - e.g. 141120 • Batch - lot AI(10) - e.g. 1234AB • Serial number AI(21) - e.g. 12345XYZ
DI + PI = UDI	GTIN or GTIN + AI(s) = UDI

According to the Rule, a device identifier is always present in a UDI. However, a *production identifier* is only required if it appears on the device label. Nonetheless, most devices include at least one piece of production information on the label, and therefore most UDIs would include a production identifier. Therefore, UDIs can be comprised of either **DI only**, or **DI and PI**.

7.1.2 UDI Labelling

The Rule requires that UDIs be presented on device labels in both human-readable format and Barcode format. GS1 Standards provide for several different barcodes that can be used as the UDI Barcode format.

The choice of GS1 barcode vary on the type of UDI:

- Whether the barcode will be read in a retail environment
- Whether the barcode will need to encode "DI only" or "DI and PI"

GTIN and barcode type per scanning environment:

	Retail	Non-Retail
DI only	EAN-13	EAN-13, ITF-14, GS1-128 and GS1 DataMatrix
DI and PI		GS1-128 and GS1 DataMatrix

7.1.3 Global Unique Device Identification Database

Whenever a device must bear a UDI, the rule requires the labeller of that device to submit information concerning the device to the FDA. The Global Unique Device Identification Database (GUDID) will serve as a reference catalogue for every device with an identifier.

The FDA has published a GUDID Draft Guidance for Industry that indicates that there will be three options/methods for Publishing/Reporting UDI and associated data to the FDA's GUDID:

- Structured input via the GUDID Web Interface
- HL7 Structured Product Labelling (SPL) submitted via the FDA Electronic Submissions Gateway (ESG)
- Use of a certified GDSN Data pool

7.2 Pharmaceuticals – EU Falsified Medicines Directive

The EU has a strong legal framework for the licensing, manufacturing and distribution of medicines. At the end of the distribution chain, only licensed pharmacies and approved retailers are allowed to offer medicines for sale, including the legitimate sale via the internet.

In July 2011, the EU strengthened the protection of patients by adopting a new Directive on falsified medicines (FMD). The ultimate goal of this Directive is to prevent falsified medicines entering the legal supply chain and reaching patients.

It introduces harmonised safety features and strengthens control measures across Europe. In particular, the FMD is including requirements that medicinal products subject to prescription shall bear safety features.

7.2.1 Scope

Products under the scope of this EU legislation are all products under prescription (unless white-listed). Products sold over the counter (OTC) are out of scope, unless black-listed. *For more detailed information on listed products, please read the full regulation.*

The Directive also specifies the following points:

- Safety Features consisting of a Unique Identifier (UI) on each pack combined with tamper-evidence
- Mandatory verification at the point-of-dispense and risk-based verification in the supply chain
- Supported by a Europe-wide "repositories system"

A mandatory authenticity feature will be printed on or attached to the outer packaging of the medicines.

The key concept of the Directive is the mandatory verification at Point-of-Dispense. This verification includes both the Unique Identifier and the tamper-evidence device on the package.

7.2.2 Timeline

The Delegated Acts provide more detailed requirements on this capability and were published on the 9th of February 2016.

The requirements will have to be implemented by healthcare supply chain actors in the EU Member States by 2019. Some EU countries has been granted an additional 6 years in order to comply. But Belgian officials have said that Belgium will follow the deadline of 2019.

7.2.3 Definition of a Falsified Medicinal Product

Any medicinal product with a false representation of:

- Its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients
- Its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder
- Its history, including the records and documents relating to the distribution channels used.

This definition does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights.

7.2.4 Data on the package and the data carrier

4 data elements represented in the data carrier are:

1. Unique Identifier – **GTIN AI (01)**
 2. Batch/Lot Number – **AI (10)**
 3. Expiry Date – **AI (17)**
 4. Serial Number – **AI (21)**
- OPTIONAL: National Reimbursement Code – **AI (71X)**

The chosen data carrier for this new Directive is a 2D DataMatrix Barcode (ECC200). The use of a **GS1 DataMatrix** barcode fully complies with the regulation. Also, only one barcode is allowed on the package. The Human readable elements need to be printed adjacent to the 2D barcode.





Koningsstraat 76 Bus 1
Rue Royale 76 Boîte 1
BE-1000 Brussel/ Bruxelles
T +32 2 229 18 80
E info@gs1belu.org

www.gs1belu.org

Helpdesk?

Barcodes: Barcodes@gs1belu.org
EDI: EDI@gs1belu.org
Data : Data@gs1belu.org
Data Quality : Quality@gs1belu.org
Website : Website@gs1belu.org