



The Global Language of Business

GS1 Healthcare GTIN Allocation Rules

GTIN Allocation Rules for the Healthcare Sector

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1 Scope and background

Unique identification provides an opportunity to differentiate, in a machine readable form, an item's identification. Such information is rapidly becoming a pre-requisite, when linked with the item's batch number (or unique serial number) and expiration date, for traceability of all healthcare products from production to delivery to the patient (point of care). This voluntary guideline was developed by the GS1 Healthcare so that, when and where product identification is required there will be consistency in the use of data structures worldwide. It also covers the specific Point-of-Sale requirements which are essential for Prescription & Non-Prescription healthcare items.

GS1 Healthcare is developing, promoting, and implementing global industry standards for solutions to prevent medical errors, combat counterfeit products and improve supply chain efficiencies throughout the healthcare industry. The initial focus has primarily been on Pharmaceutical and Medical Devices and thus this document reflects the current engaged representation. While the principles and examples given may be applied to the entire healthcare sector, further development and updates to ensure that specific examples from animal health, dental products, etc. may be added. Should a sector believe it is necessary to provide further input or additions to this document it should approach GS1 Healthcare to initiate these discussions.

-  **Note:** The GS1 Healthcare website (<http://www.gs1.org/healthcare>) is continuously updated.
-  **Note:** Terms specific to this document are defined in the Glossary of Terms (Appendix A), additional terms are found within the GS1 General Specification.

2 Introduction to Global Trade Item Number in healthcare

2.1 Definition of a GTIN

The Global Trade Item Number™ (GTIN™) is used for the unique identification of trade items worldwide. GTINs may be 8, 12, 13 or 14-digits in length. Their data structures require up to 14-digit fields, and all GTIN processing software should allow for 14 digits.

A trade item is any item (product or service) upon which there is a need to retrieve pre-defined information and that may be priced, or ordered, or invoiced at any point in any supply chain. This includes individual items as well as all their different configurations in different types of packaging.

2.1.1 GTINs in healthcare

Global Trade Item Numbers (GTINs) uniquely identify items that are traded (Pharmaceuticals, Medical Devices, etc.) in the Supply Chain. Integrity of these numbers throughout the item's lifetime is a key to maintaining uniqueness for manufacturers, wholesalers, distributors, hospitals, regulatory bodies and other Supply Chain stakeholders. A change to one aspect, characteristic, variant or formulation of a trade item may require the allocation of a new GTIN.

Brand Owners who hold the specifications of a healthcare item must properly allocate and maintain their GTINs to enable trading partners to distinguish products effectively for regulatory, Supply Chain and patient safety concerns.

This publication is based upon the GS1 GTIN Allocation Rules www.gs1.org/gtinrules and has been tailored to meet the specific needs of healthcare. While all GS1 standards are voluntary, the rules are intended to drive consistent implementation in the Global Healthcare Community.

-  **Note:** National, federal or local regulations may apply and will take precedence over this voluntary guideline. For example, some healthcare regulators may place requirements or restrictions on GTIN use within their jurisdiction.

2.1.2 Structure of a GTIN

Upon joining a GS1 Member Organisation companies receive a GS1 Company Prefix and full documentation on how to allocate GTINs to their products. The four methods to construct a GTIN are explained in detail the web site <http://www.gs1.org/productssolutions/idkeys>.

Although GTINs have an administrative structure to ensure that they are unique, they should be treated as non-significant numbers. This means that they should always be recorded and processed in their entirety; no part of the number relates to any classification or conveys any information.

- ✔ **Note:** This GTIN format is used in business transactions, especially for eCom (e.g., electronic orders, invoices, price catalogues, etc.)

The figure below shows the construct of the GTIN-13.

Figure 2-1 Example of a GTIN-13

GS1 Company Prefix								Item Reference				Check digit
N ₁	N ₂	N ₃	N ₄	N ₅	N ₆	N ₇	N ₈	N ₉	N ₁₀	N ₁₁	N ₁₂	N ₁₃

GS1 Company Prefix

- The GS1 Company Prefix consists of a GS1 Prefix and the Company Number both of which are allocated by GS1 Member Organisations. In general it comprises six to ten digits depending on the capacity needs of the company.
- The first two or three digits N₁, N₂, N₃ constitute the GS1 Prefix allocated by GS1 Global Office to each GS1 Member Organisation. It does not mean that the item is produced or distributed in the country to which the prefix has been allocated.

Item Reference

- The Item Reference is a component of the Global Trade Item Number (GTIN) assigned by the owner of the GS1 Company Prefix or U.P.C. Company Prefix to create a unique GTIN and is a non-significant number, which means that the individual digits in the number do not relate to any classification or convey any specific information. The simplest way to allocate Item References is sequentially, that is 000, 001, 002, 003, etc.

Check digit

- The check digit is the last digit. It is calculated from all other digits in the GTIN.

Figure 2-2 Example of a GTIN-14

GTIN-14 Data Structure	Indicator	GTIN of the items contained (without check digit)	Check digit
	N ₁	N ₂ N ₃ N ₄ N ₅ N ₆ N ₇ N ₈ N ₉ N ₁₀ N ₁₁ N ₁₂ N ₁₃	N ₁₄

Indicator

- The Indicator is only used in the GTIN-14 Data Structure. It takes the value 1 to 8 (see Note 1 below) and is used for lower or higher packaging levels (see section [4.4 Identification within a hierarchy](#)). The simplest way to allocate the indicator is sequentially that is 1, 2, 3... to each grouping of a trade unit.

A uniform grouping of trade items is a standard and stable grouping of identical trade items. The manufacturer or supplier has the option of either assigning a unique GTIN-13 or GTIN-12 to each grouping or assigning a unique GTIN-14 with an Indicator value of 1 to 8. These 14-digit GTINs incorporate the GTIN of the trade item (less its check digit) contained in each grouping. The check digit for each GTIN-14 is then recalculated.

The Indicators have no meaning. The digits do not have to be used in sequential order and some may not be used at all. The GTIN-14 structure for standard trade item groupings creates extra numbering capacity. Indicators can be re-used.



Note: The value 9 is reserved for variable measure items. These are rare in healthcare but an example could be gases used in operations. The amount of gas used for any given operation is variable but can be priced or ordered or invoiced in predefined quantities (e.g., cubic metres) when delivered to a hospital.

The Indicator is a digit with a value of 1 to 8. It is assigned as required by the company that constructs the identification number. It can provide up to eight separate GTIN-14 Identification Numbers to identify groupings of trade items.

The 8-, 12- or a 13-digit GTIN of the trade items contained must always be the one of the relevant levels of packaging contained, usually the lowest level. GTINs for restricted distribution must not be used in this Element String.

2.2 Healthcare items (definitions)

The legal definitions for healthcare items will differ from one country to another (see section [3 Regulators](#)). 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.

2.2.1 General definitions

2.2.1.1 Kits

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:

- 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).
- 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.

2.2.2 Pharmaceutical products

2.2.2.1 Non-prescription

A non-prescription pharmaceutical product 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. Typical examples include mouthwash, low-strength pain-killers, etc.

2.2.2.2 Prescription (Rx)

A Prescription (often referred to as a Pharmaceutical) Product (Rx) 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.

2.2.2.3 Hospital pharmacy production

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.

2.2.3 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
- disinfection 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.

2.2.3.1 Configurable devices

A configurable medical device is a product that consists of multiple components, some of which may be selected by the customer based on a list provided by the manufacturer. The possible configurations are determined by product design. In all cases, configurable medical devices are considered to be, and intended to be used as, a single trade item and may be supplied through multiple shipments.

2.2.3.2 Medical device software

Medical Device Software, as defined IEC 62304 *Medical device software – Software life cycle processes*, is a software system that has been developed for the purpose of being incorporated into the medical device being developed or that is intended for use as a medical device in its own right. Medical Device Software may be configurable, where some features or modules can be selected by the customer.

2.3 Data requirements in healthcare

2.3.1 Global Trade Item Number (GTIN)

By joining a GS1 Member Organisation the company receives a GS1 Company Prefix which gives the company the ability to create GTINs and access to the GS1 standards. The GS1 System is designed to be used in any industry or any part of the public sector so that an individual company can select to allocate GTINs using a GS1 Company Prefix from the GS1 Member Organisation of their choice. However, some Regulators impose mandatory local requirements on the use of GTIN within their jurisdiction (see [3, Regulators](#)).

Attributes (e.g. Batch Number, Expiration Date, and Serial Number) add value to the product as production control attributes when combined with the GTIN in a GS1 barcode using the GS1 Application Identifiers. Their use enables tracking & tracing systems and can contribute to improving patient safety. For more information see the general guidelines <http://www.gs1.org/healthcare>.

Within the GS1 System the following attributes may only be used in association with a GTIN.

2.3.1.1 Batch or Lot number

A Batch or Lot Number (Application Identifier (10)) associates an item with information the responsible entity considers relevant for traceability of a trade item. The number may be, for example, a production lot number, a shift number, a machine number, a time, an internal production code, or a software version number. The data is alphanumeric and length is variable up to 20 alphanumeric characters.

2.3.1.2 Expiration date

An Expiration Date (Application Identifier (17)) is often referred to as expiry date or maximum durability date and indicates the limit of consumption or use of a product (e.g., for pharmaceutical products it will indicate the possibility of an indirect health risk resulting from the ineffectiveness of the product after the date). It is always encoded as a fixed length six numeric characters with the structure YYMMDD where:

- YY = the tens and units of the year (e.g., 2015 = 15).
- MM = the number of the month (e.g., January = 01).
- DD = the number of the day of the relevant month (e.g., second day = 02).

An Expiration Date and Time may also be expressed (Application Identifier (7003)). This structure is only used when the exact expiration time is critical to patient safety.

2.3.2 Serial Number

A Serial Number (Application Identifier (21)) is typically used on medical devices that need to be individually tracked and traced (e.g., wheel chairs, pacemakers, MRI scanners).

3 Regulators

The healthcare industry is highly regulated and companies are required to comply with national, federal and/or local regulations.

This guideline has been developed as a global standard to help companies meet the key requirement of Product Identification (also an enabler for encoding batch and expiration date). The broader GS1 Global Healthcare User Group has a regulatory affairs area on the website (see <http://www.gs1.org/healthcare>). The GS1 Healthcare User Group advocates the use of global standardisation to aid compliance to the regulatory requirements of **all** countries. However, it must be stressed that national, federal or local regulations may apply and take precedence over any GS1 standard.

4 Allocating the Numbers

4.1 General Rule

A Global Trade Item Number (GTIN) is used to identify any item upon which there is a need to retrieve pre-defined information and that may be **priced** or **ordered** or **invoiced** at any point in any Supply Chain. Typically this includes the lowest level of packaging as well as higher packaging levels.

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. This principle is demonstrated in the figure below where the two products have identical ingredients and brand names but require separate GTINs as one product can be sold anywhere while the other requires a Pharmacist to distribute (because of the intended usage).

Figure 4-1 Example of product change triggering a New GTIN be allocated



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. This document aims to define globally what is meant by **significant change** in healthcare by way of practical examples.

4.1.1 Differentiation between primary package and secondary packages in a one to one (1:1) relationship

Some healthcare processes require the capability to clearly differentiate between a healthcare trade item in its primary and secondary packaging, even if they share a “one to one” (1:1) relationship. An example could be a tube of cream in a box, a vial in a box, a single, multiple quantity blister card in a box or a syringe in a unit carton. In this situation the trade item primary package and secondary package may have different GTINs assigned when required by regulation or as agreed within a trading partner relationship. GTIN allocation and the marking of GTINs is made at the discretion of the brand owner.

4.2 Responsibility

4.2.1 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 (e.g., licensed distributor, subsidiary, reseller, etc.).

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 (e.g., new language, updated software, etc.). Individual customer configuration therefore cannot impact GTIN Allocation.

4.2.2 Kitter

The kitter is the Responsible Entity that defines the kit 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.

4.3 Guidelines for Allocating Global Trade Item Numbers

4.3.1 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.

4.3.2 Lead time in re-using 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. As an example:

“Product A”, a first generation injectable antibiotic, was withdrawn from the market by its manufacturer due to declining sales. After a 10 year absence from the market, “Product A” was reintroduced by the manufacturer, in its original form and package configuration, to treat infections resistant to newer antibiotics. In this example the original GTIN may be used.

4.3.3 Prepriced merchandise

Prepricing is discouraged as a trade practice as it introduces complexity for trade item file maintenance through the Supply Chain. However, prepricing can be a mandatory requirement from the regulatory authorities therefore if the price that the consumer will pay is marked on the item, the Global Trade Item Number (GTIN) should be changed when the price marked on the item changes.

4.3.4 Trade item changes

Trade item changes are any change or improvement during the life of a trade item where the new trade item replaces the old one. Should the Brand Owner decide to create a variant (e.g., with different active ingredient) in parallel with the standard trade item, then a separate GTIN has to be allocated.

Minor trade item changes or improvements **do not** require the allocation of a different GTIN. Examples: artwork colour changes, outer packaging material change, etc.

Major trade item changes or improvements **do** require the allocation of a different GTIN. Examples: If a trade item’s quantity or measure changes or if **any pre-defined characteristics** are modified, then a new GTIN must be allocated.

4.4 Identification within a hierarchy

It is important that different levels within a hierarchy (e.g., Single Unit or Single Unit Package, Shipper or Case, Pallet, etc.) are assigned different GTINs. It is for the Brand Owner or Responsible Entity to determine the hierarchy level(s) to which a GTIN should be assigned. Typically any hierarchy level that is **priced** or **ordered** or **invoiced** at any point in any Supply Chain should receive its own GTIN. In some healthcare applications this may also be recorded and included in patient records.

A typical hierarchy level example is shown in [Figure 4-2 Example of Typical Pharmaceutical Hierarchy Levels](#). More detailed examples are provided at <http://www.gs1.org/productssolutions/idkeys>.

Figure 4-2 Example of Typical Pharmaceutical Hierarchy Levels

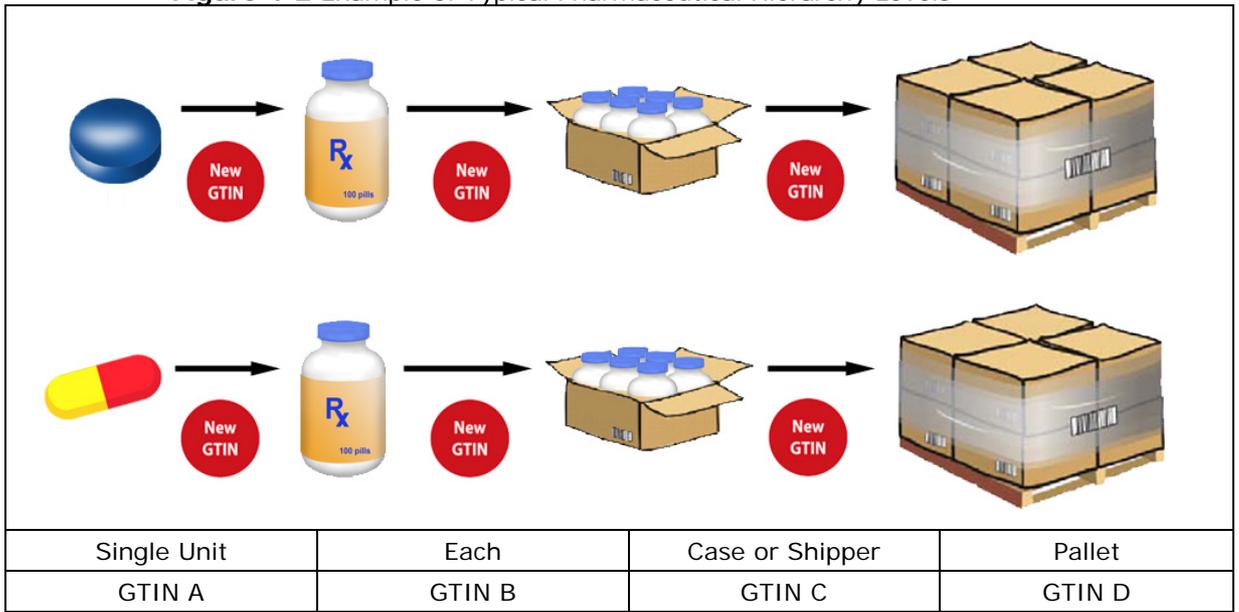
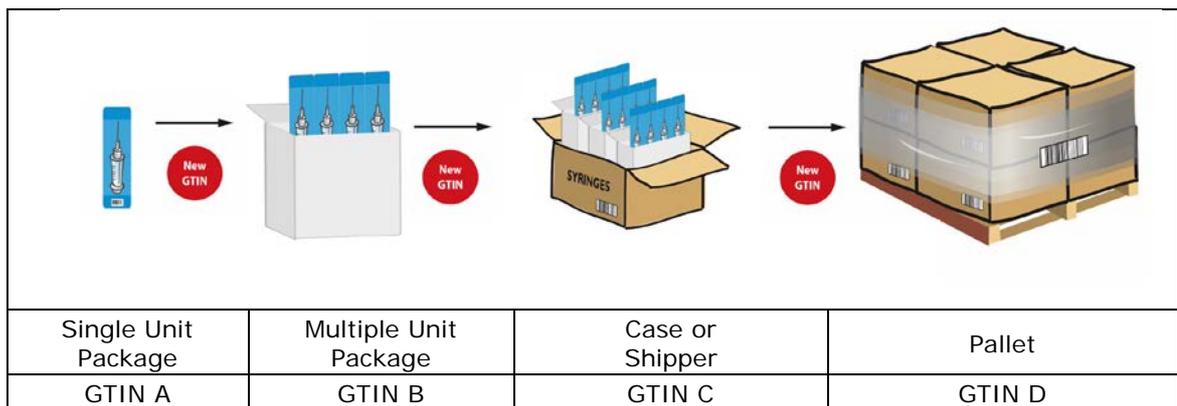


Figure 4-3 Examples of Typical Medical Device Hierarchy Levels



Note: While the hierarchy level does not impact the GTIN of a specific item, each different grouping of the same item requires a separate GTIN as shown in [Figure 4-2 Example of Typical Pharmaceutical Hierarchy Levels](#) and [Figure 4-3 Examples of Typical Medical Device Hierarchy Levels](#).

- ✔ **Note:** While GTINs are typically assigned to packaged items, the GTIN Allocation Rules cover scenarios for unpackaged items in section [5.1.1](#) Different language or target market and [5.3.6 Rules for single Unit](#)
- ✔ **Note:** The pallet or logistic level can be identified with a GTIN for trade purposes and is identified with a SSCC for logistics application.

4.5 Takeovers

4.5.1 Acquisitions and mergers

For the company being acquired, existing stocks on hand which are numbered before the acquisition or merger, keep the same Global Trade Item Numbers (GTINs). Products that are produced after the acquisition or merger may keep the GTIN allocated before the acquisition if the acquiring company maintains the GS1 Member Organisation membership.

A merger implies that a legal entity has taken over a company and has assumed responsibility for the company's GS1 Company Prefix, as well as, their assets and locations. Products that the company produced under its GS1 Company Prefix can still be produced using the same prefix after the merger, as full responsibility for the GS1 Company Prefix is unaffected. If it so desires, the new company can label all acquired products using only one of their existing GS1 Company Prefix.

The importance of ensuring trading partners are informed of any changes, in a timely manner, cannot be overemphasised. A company should be careful when centralising the allocation of all numbers under one GS1 Company Prefix, thus changing the GTIN of the existing products, which are otherwise unchanged. Centralising the allocation of all numbers under a single GS1 Company Prefix should be an exception, as it results in additional work and data file maintenance for customers. Companies should notify their GS1 Member Organisation of any legal status change, within one year, to facilitate a smooth transition.

4.5.2 Partial purchase

If a company purchases a division of a company whose GS1 Company Prefix is used in divisions not purchased, then the acquiring company must change the GTINs for products in the purchased division within one year.

In most cases the rules concerning the use of the seller's GTINs, and other GS1 Identification Keys, should be taken into consideration when drawing up the purchase contract.

At the earliest opportunity, the buyer should phase in new numbers, from its own range of numbers, for items whose brand name it has acquired. The buyer will be able to do this, for example, when packaging is redesigned or reprinted.

Best practice in healthcare is that the selling company never reallocate the numbers used on products which are divested to another company.

4.5.3 Split or spin-off

When a company splits into two or more separate companies it is necessary for each GS1 Company Prefix assigned to the original company to be transferred to only one of the new companies. Any company left without a GS1 Company Prefix will need to apply to a GS1 Member Organisation to obtain one. The decision about which of the new companies should take the original GS1 Company Prefixes should be made in such a way as to minimise the number of additional GTINs required. The decision should be part of the legal arrangements of the new companies.

It is not necessary for existing stocks of items to be renumbered. However, when any of the split or spin-off companies has trade items that are numbered with a GS1 Company Prefix that it no longer holds the company should renumber those items using its own GS1 Company Prefix when new labelling or packaging is produced. Customers should be notified well in advance of the changes.

Split or spin-off companies that retain a GS1 Company Prefix must keep a record of the GTINs created that have been allocated to items they no longer own. Best practice in healthcare is to never reallocate the numbers used on products which are divested to another company.

4.6 Data alignment

When a new GTIN is assigned to a trade item, it is essential that the Brand Owner provide the detailed information to trading partners about the item's characteristics (see section 4.3.1 Pre-defined characteristics). It is essential that the information associated with a GTIN is accurate and communicated in a timely manner.

4.6.1 Data alignment best practice

A number of actions are vital to ensure that GTINs are accurately communicated within the Supply Chain. These actions ensure that the data associated with any scanned barcode can be associated with accurate, up-to-date, data. This is particularly essential for items scanned in Healthcare Supply Chains where the absence of accurate data may have safety, product availability and/or regulatory conformance implications.

The GTIN provides a Supply Chain solution for the identification of any item and overall Supply Chain costs are minimised by all partners in the Supply Chain adhering to identical allocation rules as laid down in this publication.

5 GTIN Allocation scenarios

5.1 General Rules

Although regulations (see section [3 Regulators](#)) are extremely important in this area, most Non-Prescription items follow broadly similar allocation rules to those in the general retail environment (see www.gs1.org/gtinrules). The examples below focus on major healthcare specific scenarios not found within the general retail environment.

There is a clear overlap between Non-Prescription products and both Medical Devices and Prescription (Rx) drugs. The general principles in this section apply to any type of healthcare item.

5.1.1 Different language or target market

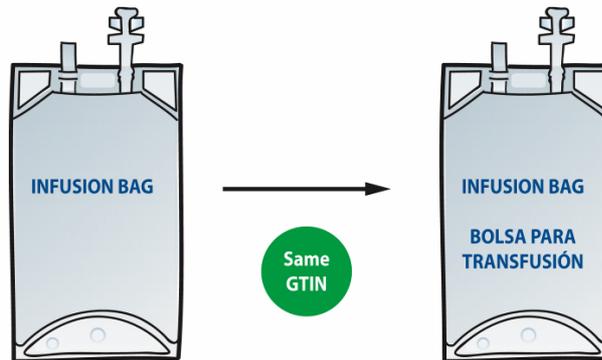
[Figure 5-1 New GTIN](#) shows two otherwise identical products - one targeted for an English speaking country, the other for a Spanish speaking country. As the two items exist in parallel and cannot be substituted (due to market acceptance and local labelling laws) a new language version to be sold in one Market/Country requires a different GTIN than the other that is sold in a different Market/Country.

Figure 5-1 New GTIN



5.1.2 Additional language on the packaging sold in several markets

Unlike the single language packaging (see section [5.1.1 Different language or target market](#)) many products are packed for multiple countries and markets. Where there is an addition to an existing language cluster, the GTIN will remain the same.

Figure 5-2 Addition to an Existing Language Cluster - Same GTIN


5.1.3 Changes in packaging materials or minor artwork changes

Minor artwork changes or a minor change in packaging materials do not require the allocation of different GTINs.

Typically the gross dimensions of a trade item communicated via the Item File that do not affect net trade item quantity or measure do not impact the GTIN assignment. If dimensions are relevant anywhere in the supply chain, the general rule is that if any gross dimension (e.g. length, depth, weight, etc.) changes by more than 20%, a new GTIN is required. Changes below 20% may require a new GTIN at the discretion of the brand owner.

Figure 5-3 Minor Change in Packaging Materials - Same GTIN


Note: Minor changes - those which are not relevant to trading partners because they do not impact the information concerning the exchange of products - do not require a change of GTIN.

5.1.4 Promotions

Promotions are normally short-term modifications to the way the item is presented. Promotions related to price do not impact GTIN allocation.

Figure 5-4 Promotions Related to Price - Same GTIN



Note: Any promotion impacting the content of the product, or requiring a new Regulatory Filing, is considered a major change and a new GTIN must be assigned.

5.1.5 Declared change in net content

Any modification which leads to a declared change in the net content of a healthcare item requires a new GTIN to be assigned. Examples include: number of tablets in a package; the number of sterile wipes in a pack; the net volume of 400 grams in 4 helpings of 100 grams (for adult use) changed to 400 grams in 8 helpings of 50 grams (for a child), etc.

Figure 5-5 Declared Change in Net Content - New GTIN



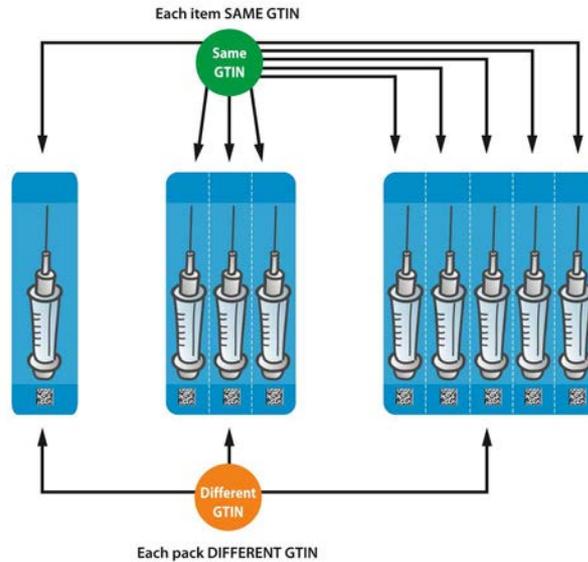
Information systems need to distinguish between old and new healthcare items where there is a declared change in net content. Failure to distinguish old and new could lead to medical error and/or inaccurate unit pricing.

Note: Improvements in manufacturing tolerances, that do not impact the declaration on the product in any way, do not require a GTIN change as the modification is only relevant to the manufacturer.

5.1.6 Groupings of same item containing different quantities

It is essential that each different packaging level (e.g., Single Unit Package, Shipper, Case, etc.) be assigned a different Global Trade Item Number (GTIN). The example below shows otherwise identical syringes in packs of one, three, and five:

- The GTIN for each individual item is the same independent of any lower or higher packing levels or use as part of a larger Healthcare Kit - see section [5.1.8, Kits](#)
- Each grouping (the pack of one, three and five below) requires a separate GTIN.

Figure 5-6 Groupings of the same item containing different quantities


5.1.7 New/additional pallet layouts that co-exist permanently with the original layout

The pallet-layout does not impact GTIN allocation of items on the pallet (see section [5.1.6. Groupings of same item containing different quantities](#)) and a GTIN is not normally required at the pallet level. However, if the market requires additional pallet configurations to be made available for ordering purposes, then different GTINs are required for each pallet-pattern and/or pallet-layout.

Figure 5-7 Additional pallet configurations for ordering purposes - New GTIN


5.1.8 Kits

A kit is a non-homogeneous combination of components intended for one specific healthcare purpose and is priced, ordered and invoiced as a single unit (see section [2.2.1.1, Kits](#)). The Kitter is the Responsible Entity and therefore allocates the GTIN to the kit.

All kits should be identified with a GTIN. Any GTIN attributes (e.g. Batch/Lot, Expiry, etc.) used and associated with the GTIN for additional identification are determined by the Responsible Entity of the trade item and/or by the requirements set by the controlling regulatory body. As a best practice, all kit components should be listed on the product label. At a minimum, all kit components should be contained in a product catalogue, database or similar document that references the kit GTIN.

The following GTIN change rules apply:

- Adding or removing kit components requires a new GTIN. (see [Figure 5-8 Addition of a kit component](#))
- When kit components are specified (by GTIN and/or brand owner item number), and that kit component is substituted, the kit GTIN must be changed. (see [Figure 5-9 Kit with specified components](#))
- When kit components are listed by description only (i.e. no GTIN or brand owner item number), the kit manufacturer may substitute that kit component (maintaining form, fit and function) without having to change the kit GTIN. (see [Figure 5-10 Kit with unspecified components](#))

Figure 5-8 Addition of a kit component

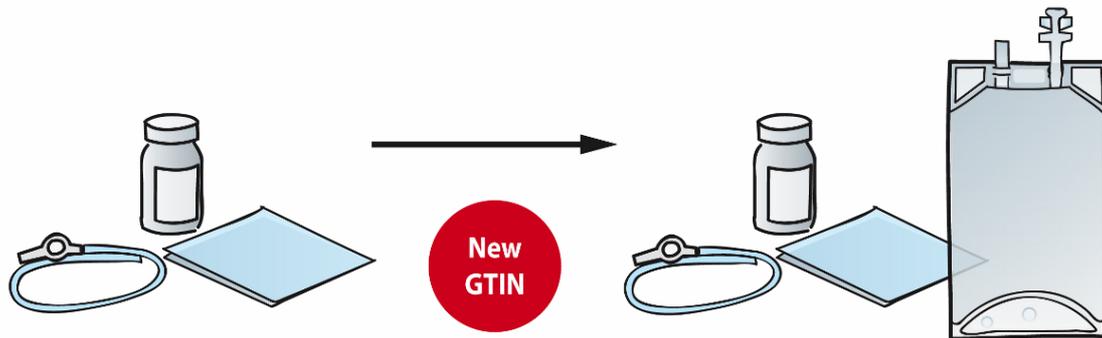


Figure 5-9 Kit with specified components

GS1 Suture Removal Kit			New GTIN	GS1 Suture Removal Kit			Item GTIN C GTIN D GTIN E GTIN F
GTIN A				GTIN H			
Item	Description	Quantity		Item	Description	Quantity	
GTIN C	Forceps	1		GTIN C	Forceps	1	GTIN C
GTIN D	Suture	2		GTIN G	Suture	2	GTIN D
GTIN E	Scissors	1		GTIN E	Scissors	1	GTIN E
GTIN F	3" x 3" Gauze	1		GTIN F	3" x 3" Gauze	1	GTIN F

Figure 5-10 Kit with unspecified components

GS1 Suture Removal Kit GTIN A		Same GTIN	GS1 Suture Removal Kit GTIN A	
Description	Quantity		Description	Quantity
Forceps	1	Forceps	1	
Suture "A"	2	Suture "B"	2	
Scissors	1	Scissors	1	
3" x 3" Gauze	1	3" x 3" Gauze	1	

5.2 Regulated pharmaceuticals (Prescription and non-prescription)

5.2.1 General rules

As with the General Rules that apply to all healthcare items (see section [4.1 General Rule](#)), compliance to regulatory requirements always takes precedence (see section [3 Regulators](#)). The additional general rules that apply specifically to the Regulated Pharmaceuticals (Prescription and Non-Prescription) are:

- Any change to the Regulatory Filing of a product (for example triggered by a formulation, usage, concentration/potency, etc. change) will lead to new GTIN.
- In addition to the product identification (GTIN), Batch Number, Expiration Date and/or Serial Number are sometimes required in barcode form.
- In the case where these products are prepared specifically for an individual patient (for example in a hospital pharmacy) the normal GTIN rules may not be applicable. For these specialist 'one-off' preparations, it is suggested to barcode and number the product so that it is uniquely attributed to the individual patient.

5.2.2 Rules for single unit

Products in most sectors are currently identified at multiple hierarchy levels (see section [4.4 Identification within a hierarchy](#)). The lowest hierarchy level within the GS1 System is generally referred to as the "Each" level. Identification and marking of that "Each" level of hierarchy for Regulated Healthcare Trade Items is covered in the Section titled *Healthcare Secondary Packaging (Regulated Healthcare Retail Consumer Trade Items)* of the GS1 General Specification.

In healthcare lower levels of a hierarchy are often referred to as "Level Below the Each" or "Single Unit" or "Single Unit of Use". For the purposes of this document we will refer to this level as Single Unit.

Examples of a Single Unit include an unpackaged unit, perforated blister cell, ampule, vial or tube. Identification and marking requirements of these trade items are covered by the section *Healthcare Primary Packaging (Non-Retail Trade Items)* of the GS1 General Specification.

Additional rules that apply specifically to this hierarchy identification of packaged or unpackaged single unit items, not already covered by other sections of the General Specifications, are covered in the following sections.

5.2.3 Single unpackaged pills / tablets / capsules / caplets and those packaged in blister cells

A GTIN should be allocated to a single unit. GTIN allocation is the responsibility of the Responsible Entity responsible for the single unpackaged unit. The Brand Owner responsible for GTIN allocation for a Healthcare Trade Item may vary based upon the party who is the Responsible Entity. These GTINs allocated to quantities of one are not expected to be marked using AIDC technology (e.g.

barcodes). Individual perforated blister cells are treated as a Healthcare Primary Package and should be identified and marked as such.

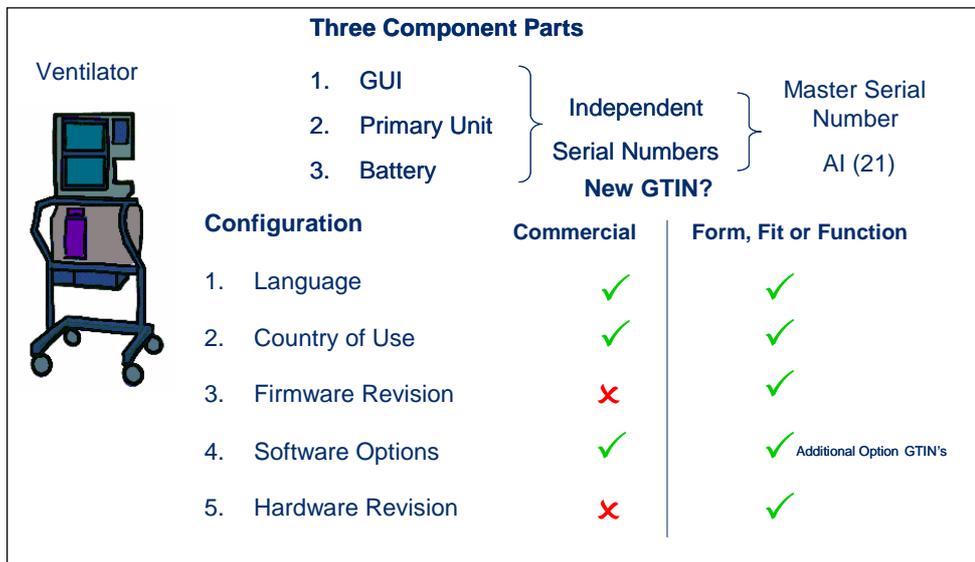
5.2.3.1 Unpackaged solutions / liquids / creams / gels / powders / aerosols

A GTIN is not expected to be allocated to an unpackaged single unit within multiple/variable quantity, either packaged or unpackaged, unless required by regulation or as agreed within a trading partner relationship. Regardless, GTIN allocation is made at the discretion of the brand owner. GTINs assigned to these unpackaged items are not marked using AIDC technology (e.g. barcodes).

5.3 Medical devices

5.3.1 General rules for medical devices

Figure 5-11 Example of a medical device



As with the General Rules that apply to all healthcare items (see section [4.1 General Rule](#)), compliance to regulatory requirements always takes precedence (see section [3 Regulators](#)). The additional general rules that apply specifically to Medical Devices are:

- Any change to the product form, fit, or function, in addition to differences or changes in intended use requires a new GTIN.
- In the case where these products are prepared specifically for a patient, normal GTIN Allocation Rules may not be applicable. For these specialised devices, the device should be uniquely identified and marked.

Medical devices that require additional consideration beyond the General Rules are described in the following sections:

- Configurable medical devices (section [5.3.2 Configurable medical devices](#))
- Software that is considered a medical device (section [5.3.3 Medical device software](#))
- Barrier Packs (Sterile Packaging) (section [5.3.5 Barrier packs \(Sterile packaging\)](#))
- Multiple medical devices not sold separately (section [5.3.6.1 Multiple devices never sold separately / Single-Use Non-sterile devices](#))
- Multiple use medical devices (section [5.3.6.2 Multi-use non-sterile devices](#))

The above Medical Devices may be grouped into healthcare kits. See section [5.1.8 Kits](#) for these GTIN Allocation Rules.

5.3.2 Configurable medical devices

A configurable medical device is a product that consists of multiple components (See section [2.2.3.1 Configurable devices](#) for definition). These components, and how they are designed to interact with each other, establish the identification requirements for the complete device. A configurable medical device is identified by its GTIN and applicable variable data attributes (e.g. Batch or Lot, Serial Number, Expiration Date, Production Date, etc.), thus enabling configurations of the medical device to vary by combinations of components, while maintaining the same GTIN except as noted below.

As stated in section [5.3.1 General rules for medical devices](#), a change in form, fit, or function affecting intended use, requires a GTIN change. Mandatory components are those that are required to deliver the functionality of the device. Changes to or the removal of, a mandatory component, impacting device form, fit or function, require a GTIN change.

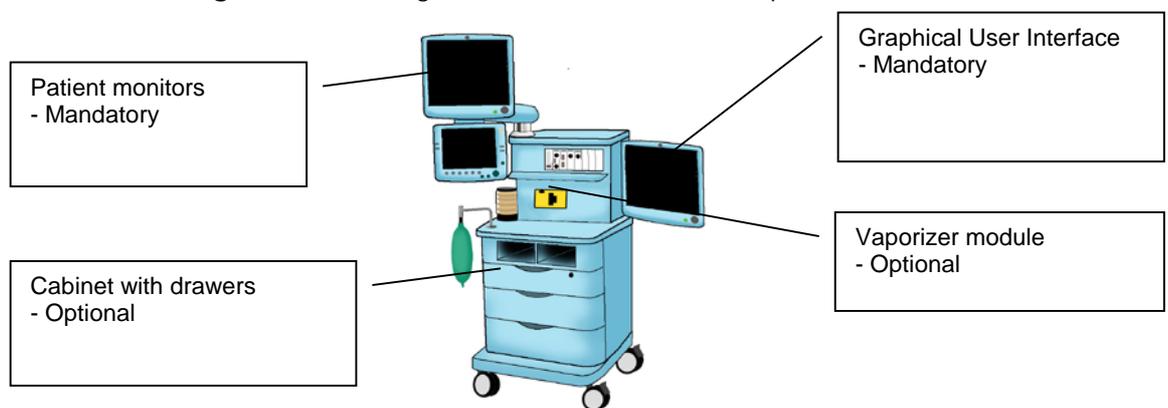
The addition of new components (that do not alter form fit or function affecting intended use) to a mandatory component selection list does not require a GTIN change.

Configurable medical devices may also include optional components, which may be included in a configuration of the medical device. Optional components provide features or extensions to functions. Changes to optional components impacting device form, fit or function, require a GTIN change. Similarly, removal of optional components from the set of available components requires a GTIN change. However, replacement of an optional component with a functionally equivalent component would not require a new GTIN. The addition of new optional components to those available for the configurable medical device does not require a GTIN change.

The configurable medical device example below includes the following components for purposes of illustrating mandatory and optional components.

- Graphical User Interface (GUI) – mandatory component
- Patient monitors – mandatory component
- Cabinet with drawers – optional component
- Vaporizer module – optional component

Figure 5-12 Configurable medical device example



5.3.3 Medical device software

Medical Device Software is a software system developed for the purpose of being incorporated into a medical device or is intended for use as a medical device in its own right. Software within the scope of these rules is a trade item and is priced, ordered, or invoiced.

Medical Device Software may be structured similar to Configurable Medical Devices, including mandatory and optional features, which are similar to device components, see section [5.3.2 Configurable medical devices](#).

The example in section [5.3.2 Configurable medical devices](#) includes medical device software that operates the device. This software may be configured based on selected software features and device components. For example, if an additional patient monitor is selected as an optional

component, the software must be configured to enable this component (patient monitor). In such cases, the GTIN assigned to the software does not require a GTIN change.

Medical Device Software that is distributed using a physical medium shall be identified with the same GTIN on the physical medium as that assigned to the software itself.

Once installed, medical device software shall be identifiable with its assigned GTIN when separated from its packaging or physical documentation.

5.3.3.1 Changes to medical device software

Changes to software occur throughout the life of the device. For medical device software, **minor** changes shall not require a new GTIN. Examples of **minor** changes include bug fixes, aesthetics, usability enhancements, security patches, or operating efficiency.

A **major** change in medical device software adds to, or changes, functionality and requires a new GTIN. Examples of **major** changes include new or modified algorithms, database structures, architecture, new user interfaces, or new channels for interoperability.

5.3.4 Inclusion of a Certification Mark

Within the healthcare sector there are many examples of certification marks. A certification mark is a symbol, logo or wording on a product that declares conformance to a regulated set of criteria (e.g., European Certification Mark CE). When a product is changed to include a certification mark (which was not previously shown on the packaging or product itself) a new GTIN should be allocated for markets where the certification mark is of particular relevance. It is a key principle of GTIN Allocation that the GTIN identifies uniquely the product and its packaging configuration.

Figure 5-13 Inclusion of a Certification Mark – New GTIN

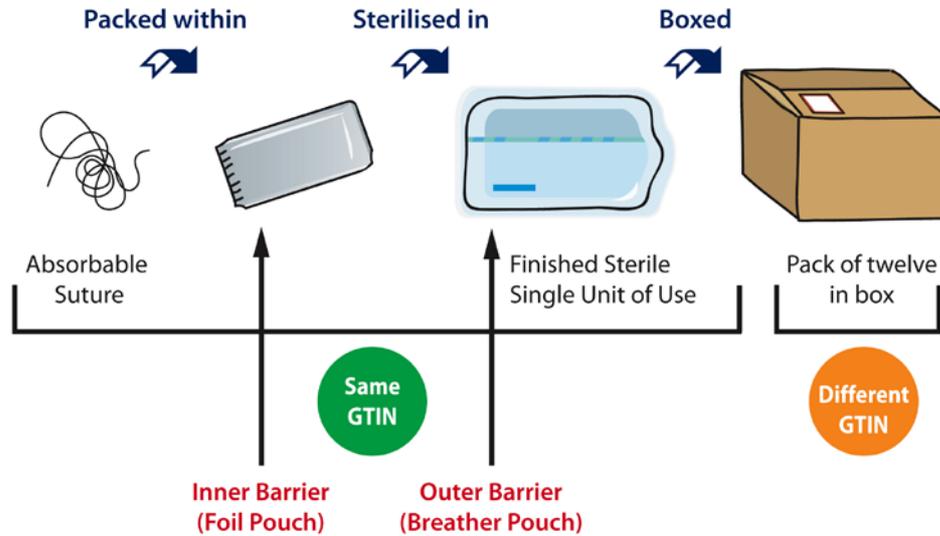


Note: Brand owners are responsible for internal control of their inventory and any return systems. It is important that such systems, as well as phase-in & phase-out logistic management, can distinguish between 'old' and 'new' product. When this can be effectively achieved, for example using the batch number or product variant, there is no need to allocate a new GTIN in the scenario above. It should also be noted that when a certification mark is added to enable sales in a new country/market it has no impact on countries/markets where the product was previously sold – in this case there is no need to allocate a new GTIN in the scenario above.

5.3.5 Barrier packs (Sterile packaging)

As outlined in section [4.4 Identification within a hierarchy](#) the general rule is that each packaging level requires a separate GTIN. However, for certain items, particularly sterile items, the multiple barrier packaging is not considered a Packaging Level for GTIN Allocation.

The example below shows a typical product where the sterilisation requires several packaging levels (double barrier packaging). When the suture is used certain packaging levels may only be opened in a sterile environment, however, the same GTIN is used for the item and the 'sterile' barrier package level as the key principles for GTIN Allocation are the commercialisation of the product (e.g., different for pricing or ordering or invoicing?) and the function (e.g., changes the intended usage?) and the sterile packaging levels have no impact on commercialisation or function.

Figure 5-14 Barrier packs (Sterile packaging)


5.3.6 Rules for single Unit

Products in most sectors are currently identified at multiple hierarchy levels (see section [4.4 Identification within a hierarchy](#)). The lowest hierarchy level within the GS1 System is generally referred to as the “Each” level. Identification and marking of that “Each” level of hierarchy for regulated healthcare trade items is covered in the Section titled Healthcare Secondary Packaging (Regulated Healthcare Retail Consumer Trade Items) of the GS1 General Specification. In healthcare lower levels of a hierarchy are often referred to as “Level Below the Each” or “Single Unit” or “Single Unit of Use”. For the purposes of this document we will refer to this level as Single Unit.

Examples of a Single Unit include an unpackaged unit, a syringe, a glove, a swab, a scalpel or a blood pressure cuff. Identification and marking requirements of these trade items are covered by the section Healthcare Primary Packaging (Non-Retail Trade Items) of the GS1 General Specification.

Additional rules that apply specifically to this hierarchy identification of packaged or unpackaged single unit medical devices, not already covered by other sections of the General Specifications, are covered in the following.

5.3.6.1 Multiple devices never sold separately / Single-Use Non-sterile devices

Single use, non-sterile, medical devices packaged as a multiple (e.g. cotton swabs) or medical devices only traded at the Primary or Secondary Packaging Levels (e.g. a box of gloves) may also require GTIN allocation. GTIN allocation is the responsibility of the Responsible Entity legally responsible for the single unpackaged unit. The Brand Owner responsible for GTIN allocation for a Healthcare Trade Item may vary based upon the party who is the Responsible Entity.

GTINs allocated to quantities of one are not expected to be marked using AIDC technology (e.g. barcodes). Marking of GTINs is made when required by regulation or as agreed within a trading partner relationship.

Examples of multiple devices never sold separately include high quantity screws/pins, gloves/gowns, swabs, tape, etc. and examples of single-use non-sterile devices include gauze, swab, tissue, etc.

5.3.6.2 Multi-use non-sterile devices

A GTIN should be allocated to a single unit. GTIN allocation is the responsibility of the Responsible Entity accountable for the single unit in that state, either packaged or unpackaged, per regulation,



legal, or customer requirements. An example of a Multi-Use Non-Sterile Device would be a blood pressure cuff.

These GTINs, allocated to quantities of one, may be marked using AIDC technology (e.g. barcodes) at the discretion of the Brand Owner.

A Glossary of terms

Term	Definition
Application Identifier	The field of two or more characters at the beginning of an Element String that uniquely defines its format and meaning.
Brand Owner	The party that is responsible for allocating GS1 System Identification Keys. The administrator of a GS1 Company Prefix.
GS1 Company Prefix	Part of the GS1 System identification number consisting of a GS1 Prefix and a Company Number. The Company Number is allocated by GS1 Member Organisations. See also U.P.C. Company Prefix. GS1 Member Organisations assign GS1 Company Prefixes to entities that administer the allocation of GS1 System identification numbers. These entities may be, for example, commercial companies, not for profit organisations, governmental agencies, and business units within organisations. Criteria to qualify for the assignment of a GS1 Company Prefix are set by the GS1 Member Organisations.
EPC	Electronic Product Code is an identification scheme for universally identifying physical objects via RFID tags and other means. See http://www.gs1.org/epcglobal
GS1 General Specifications	Defines the GS1 System data and application standards related to the marking and automatic identification of trade items, locations, logistic units, assets, and more using barcode, RFID, and GS1 Identification Keys.
GS1 Global Office	Based in Brussels, Belgium, and Princeton, USA, is an organisation of GS1 Member Organisations that manages the GS1 System.
GS1 Member Organisation	A member of GS1 that is responsible for administering the GS1 System in its country (or assigned area). This task includes, but is not restricted to, ensuring brand owners make correct use of the GS1 System, have access to education, training, promotion and implementation support and have access to play an active role in GSMP.
GS1 system	The specifications, standards, and guidelines administered by GS1.
GTIN	Global Trade Item Number used to identify any item (product or service) upon which there is a need to retrieve pre-defined information and that may be priced, or ordered, or invoiced at any point in any Supply Chain.
Item Reference	A component of the Global Trade Item Number (GTIN) assigned by the brand owner to create a unique GTIN.
Kit	A collection of non-homogeneous, separable components that are identified, purchased, and supplied as a single trade item for a specific clinical or commercial purpose.
Kitter	The Responsible Entity that defines the kit contents, specifications and labelling. The kitter may or may not assemble kits, and may engage a third party to produce the finished trade items.
Medical device	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 any medical purpose.
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.
Responsible Entity	The party responsible for the safety and effectiveness of the medical product at a moment in time in its lifecycle, according to the approved regulatory file (including labelling) and regulatory/legal/professional obligations associated with the medical product (e.g. Brand Owner, Repackager, Hospital Pharmacy, etc.).
Rx (Medical Prescription Product)	A drug or medicinal specialty that requires a medical 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.

Term	Definition
Single Unit	Single item of medicine/medical device without any package, for example the single tablet in a blister or bottle, the syringe as such.
Single Unit Package / Blister	A Healthcare Primary Package that contains one discrete pharmaceutical dosage form. I.e. a tablet, a certain volume of a liquid or that is the immediate package for a medical device like a syringe. A number of single units may be attached to each other, but are easy to separate through a perforation.
Unit of Use	Refers to an individual unit package that is used to make up the patient-specific prescription that is prescribed for administering to a patient.