The Global Language of Business

GS1 Healthcare GTIN Allocation Rules Standard

GTIN Allocation Rules for the Healthcare sector

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9.0.1	July 2015	Valerie Hoste	Applied new GS1 branding and errata fix to add figure heading 5-11 (example of a medical device)
9.0.2	Dec 2015	David Buckley	Errata fix, wrong cross-references in section 5.1.8 and fixed corrupted figure cross-references
10.0	Jun 2020	Pete Alvarez	Work Request 18-294. Conducted complete review of the entire document, clarified and updated content throughout. Harmonised with the GTIN Management Standard as appropriate including matching table of content for consistency and cross reference. Added information for Clinical Trials.
11.0	June 2026	Neil Piper and Pete Alvarez	Work Request 25-000010. Conducted complete review of the entire document, clarified and updated content in various sections, added content referenced from International Medical Device Regulators Forum (IMDRF) for consistency with medical devices.

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1 Introduction

The Global Trade Item Number® (GTIN®) provides a global standard by identifying any trade item upon which there is a need to retrieve predefined information and that may be priced, or ordered, or invoiced at any point in the supply chain.

The Healthcare GTIN Allocation Rules are designed to help healthcare industry make consistent decisions about how to manage the unique identification of both regulated and non-regulated healthcare trade items. These rules have been developed in accordance with the GS1 Global Standards Management Process (GSMP) and are considered a part of the GS1 system of standards. When all partners in the supply chain adhere to the Healthcare GTIN Allocation Rules overall costs are minimised while efficiencies and patient safety improve.

The unique identification of trade items is critical to maintaining operational efficiencies that business partners rely on to exchange information about them in consistent ways, as well as ensuring the smooth operations of global supply chains.

Additionally, the unique identification of healthcare trade items is crucial when complying with various regulations across the globe. Finally, the communication of unique identification changes between trading partners is essential to ensure the right trade item is made available when needed.

Note: The term trade item by definition encompasses products, i.e. physical entities, as well as services see GS1 General Specifications - *section 2.1.1* and *section 4.2.2* Throughout the document the term "product" will be used for denoting trade items to which GTINs are allocated. Businesses wishing to allocate GTINs to services should be aware that the general principles of GTIN allocation apply to their services, as well, even though some specifics might not be pertinent.

Note: This GS1 Healthcare GTIN Allocation Rules Standard SHALL NOT be used for identifying non-new trade items. For rules on identifying non-new trade items, see GS1 General Specifications, *section 2.1.15*

1.1 Purpose and regulatory disclaimer

This document aims at providing a globally harmonised framework for the implementation of the GS1 standards in order to improve supply chain efficiency and ensure patient safety.

Important: The Healthcare GTIN Allocation Rules represents a minimum requirement. Please be advised that there may be regulation(s) in your market area that are more stringent and SHALL be adhered to.

1.2 Scope

GS1 standards help improve supply chain operations, process efficiency, and comply with regulatory requirements to improve patient safety. This document provides clear rules for the allocation of the Global Trade Item Number (GTIN) to healthcare trade items in general and especially to products, such as medicines and medical devices.

Some of the rules included are not applicable to other sectors and are not included in the GTIN Management Standard. Every effort has been made to harmonise rules that appear in both documents.

Note: Definition of terms are found in section 5 of this document and on the online glossary on the GS1 website and in the GS1 General Specifications.

Note: Refer to the GS1 Healthcare website for general information.

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1.3 Guiding principles

The following guiding principles should be considered by the brand owner when developing a GTIN assignment strategy for a new product and when introducing changes to an existing product.

- Is a care provider, consumer and/or trading partner expected to distinguish the changed or new product from previous/current products?
- Is there a regulatory or liability requirement to disclose a change to the consumer and/or trading partner?
- Is there a substantial impact to the supply chain (e.g., how the product is shipped, stored, received, or handled in the clinical setting)?

Note: At least one of the guiding principles must apply for a GTIN change to be required.

The Guiding principles above are designed to distinguish trade items by means of unique GTINs. Note that in certain scenarios, distinction may be achieved by different means. (Please refer to *section* 2.3.1 and *section* 2.5.2)

1.4 GTIN non-reuse

An allocated GTIN SHALL NOT be reallocated to another trade item. Healthcare companies must ensure that GTINs allocated to healthcare trade items SHALL never be reused.

Exception: 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 Healthcare GTIN Allocation Rules or the GTIN Management Standard.

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.

Note: GTINs assigned to healthcare products have always been governed by a non-reuse policy. Outside of healthcare, the general GTIN non-reuse rule went into effect on 1 January 2019 in response to digital business demand. GTINs discontinued and withdrawn from the market prior to 1 January 2019 may be considered for reuse one final time (*). However, companies are strongly advised to follow the non-reuse rule for **all** GTINs to avoid risks of conflicting data.

(*) If a GTIN was withdrawn prior to 1 January 2019, the previously applicable rules must be adhered to.

For more information refer to *section 4.2.5* of the GS1 General Specifications, GTIN non-reuse section.

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2 GTIN Allocation Rules

Although regulations are extremely important in this area, most non-regulated healthcare products follow allocation rules that are similar to those in the general retail environment (see GTIN Management Standard). This document includes allocation rules needed in the healthcare sector which are not found within the general retail environment.

The allocation rules in this section apply to any type of healthcare item.

Below are the rules that define when a GTIN SHALL be assigned to a new product, a changed (replacement) product or an equivalent product in order to be in conformance with the Healthcare GTIN Allocation Rules.

Note: **Equivalent** – A product which can be substituted for the existing trade item based on supplier-defined functional equivalence to the trade item in a specific target market.

- For example, when the regulatory content of a product label differs in a way that impacts License or Registration in a particular market and limits distribution channels, it MAY require the product to be uniquely identified for supply chain purposes and regulatory control using a unique and separate GTIN.

Remember that all the Healthcare GTIN Allocation Rules and the three guiding principles need to be taken into consideration when making the final decision of whether or not to change a GTIN.

2.1 New product introduction

A "new product" is defined as a product that does not currently exist or has not been available for sale and is an addition to the brand owner's portfolio/is new to the market.

Any new product requires the assignment of a new GTIN.

2.1.1 Defining a new product compared to a product change

When making decisions about product identification, it is important to understand the differences between a NEW product and CHANGES to an existing product.

New products are those which do not currently exist in a brand owner's product offering and are new to the market. A new product considered an "addition" to an existing product offering. GS1 standards and the Healthcare GTIN Allocation Rules require that if a product is new, it should always be assigned a new GTIN to accurately distinguish the new product from those currently available in the market or previously existing product that has been discontinued.

Changes to existing products are considered "replacement product" as determined by the brand owner. The Healthcare GTIN Allocation Rules define that a new GTIN is required when a change to certain attributes of an existing product change such that a new GTIN is required.

New product: New products are those which do not currently exist in a brand owner's product offering and are new to all markets.

Product change: An existing product, currently in the brand owner's portfolio and available in the market whose attributes have been changed.

2.2 General rules: Product changes pertaining to packaging for both Medical Devices and Pharmaceutical Products

This section contains GTIN Allocation Rules that apply to both Medical Devices and Pharmaceutical products. These rules address changes related to packaging of the product including text and packaging inserts such as leaflets. The rules in this section exclude changes made directly to the function/formulation of the product itself (i.e. a Medical Device or a Pharmaceutical product).

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2.2.1 Different language on packs and leaflets that are part of a trade item

This rule provides guidance on the allocation of GTINs to trade items regarding the addition and removal of languages based on the intended target market in which the product will be sold. This covers the language printed on the package itself as well as manuals or leaflets contained in the packaging that are considered part of the trade item.

Any change to language that impacts where a product can be sold or how trading partners and end users interact with it or how the product can be distributed, MAY require the assignment of a new GTIN. If a language addition or removal is required then manufacturers have an obligation to manage this through their change control process and may takes steps such as removal of registration, removing product listing and ceasing distribution of product.

Hierarchy levels of GTIN assignment:

- The GTIN is assigned at the hierarchy level in which the language is listed (i.e. the packaging level that contains the specific language).
- A unique GTIN is assigned at every higher hierarchy level.

Example business scenarios that require a new GTIN:

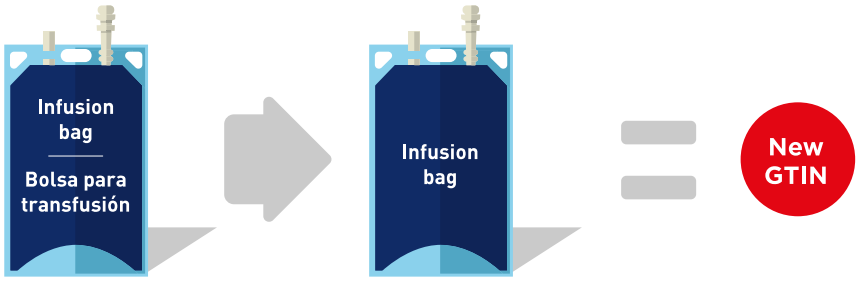
- Single language products with different target market/country.

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 target market/country requires a separate, unique GTIN than the other sold in a different target market/country.

Figure 2-1 New product - new GTIN

- When a language is removed from a multilingual package, a new GTIN SHALL be assigned.

Figure 2-2 Removal of a language from the package - new GTIN



Manuals and leaflets contained in the trade item

If a manual or leaflet is included in the product package, it is considered to be part of the trade item identified with a GTIN. Therefore, the language rules above apply.

In cases where there is more than one leaflet included in the product package, the rules above regarding removal and addition of languages apply.

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Over-labelling for a specific target market

When a label is placed on the product or package which obscures the previous information, in part or in whole, (i.e. is no longer totally visible) without reproducing the obscured information on the label **as originally represented** a new GTIN shall be assigned.

Note: When additional labelling is added that does not conceal the previous information, a new GTIN is not needed.

Example of minor artwork modification where a new GTIN is not needed:

Minor artwork or other minor modifications to packaging, which are not relevant to trading partners because they do not impact the information concerning the exchange of products, do not require the allocation of different GTINs.

Figure 2-3 Minor updates to packaging - same GTIN

Additional language on the packaging sold in several markets

Unlike the single language packaging, many products are packed for multiple countries and markets. When there is an additional language added to a trade item with an existing language, the GTIN remains the same.

Figure 2-4 Addition of a language to an existing package - same GTIN

Additional information:

- Consider applicable target market regulations related to language requirements in which the product will be sold.
- Some target markets require more than one language, consult local regulations.

2.2.2 Management of language and content changes of digital leaflets online

This rule applies to digital leaflets such as electronic Product Information Leaflets (ePIL) and electronic Instructions for Use (eIFU) available only online. In cases where the content and information are documented exclusively on the online leaflet, and not on a paper leaflet contained inside the trade item, the GTIN of the Trade Item does not have to change as long as the organisation responsible for the content (i.e. the manufacturer) has implemented a procedure for

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ensuring content changes always represent the latest and complete information of the particular product.

Note: The organisation responsible for the leaflet content assumes the responsibility to inform their trading partners and direct end user customers of the change where applicable.

Note: This rule does not currently apply to situations where the trade item includes both a paper leaflet or manual and a digital version of it.

2.2.3 Assignment of GTINs within a trade item hierarchy

This rule explains the assignment of GTINs to all levels of a trade item hierarchy (e.g., unit of use / single unit, each, inner pack, case, pallet, etc.). A trade item hierarchy level is assigned a GTIN when there is a need to retrieve predefined information and it may be priced, or ordered, or invoiced at any point in the supply chain. In some instances, this may also be referred to as the packaging hierarchy. The brand owner determines the hierarchy level(s) to which a GTIN is assigned.

Information on marking (e.g. using barcodes) for Regulated Healthcare Trade Items is covered in the section titled *Healthcare Secondary Packaging (regulated healthcare retail consumer trade items)* of the GS1 General Specifications.

Note: Higher levels of packaging, such as a case or pallet, can be identified with a GTIN when it is identifying a trade item. If trade items are grouped for the purpose of transport and/or storage, the grouping would be classified as a logistics unit and identified with a Serial Shipping Container Code (SSCC). A case, pallet or other trade item grouping can be assigned both a GTIN for product identification and SSCC for logistics purpose. For more information on SSCC refer to the GS1 General Specifications.

Unit of Use / Single Unit

Products in most sectors are identified at multiple packaging hierarchy levels (see section 2.2.7). The lowest hierarchy level of trade items within the GS1 System is traditionally referred to as the "each" level. The "each" level trade item may contain more than one unit of use. In this case there may be the need to identify levels below the 'each' down to the single unit or unit of use. For the purpose of this rule, 'single unit' and 'unit of use' are synonymous.

For levels below the each that are not individually labelled, unit level identifiers may be assigned for internal traceability or patient level documentation, even though physical marking at these levels is generally not required unless mandated by specific regulations. Across both medical devices and pharmaceuticals, the principle remains that identification must reliably support traceability and supply chain integrity, while the decision to mark or code levels below the each depends on regulatory requirements and operational needs.

Note: Depending on the target market, labelling requirements for the level below the each (e.g. single unit) might apply.

Hierarchy levels of GTIN assignment:

- A GTIN is assigned at the "each" level.
- Higher levels of packaging are assigned a separate, unique GTIN at each level if these levels are considered trade items. See section 2.2.7 for more information about Pack/case quantity.
- Levels below the 'each', down to the unit of use / single unit should have a unique GTIN assigned if it supports traceability and supply-chain integrity, for instance if the product is intended for more than one patient. However, it may or may not be marked on levels below the each.

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To comply with medical device UDI regulations, it is recommended for medical devices that there is only a single level of a product below the lowest packaged level to ensure accuracy in supply chain and ensure traceability.

Note: Although it is acknowledged that rare exceptions occur where more that one "level below the each" exist, it is recommended that for medical devices there be only a single level of a product.

Example business scenarios for GTIN packaging hierarchy levels:

In the examples to come, the 'each', 'case', and 'pallet' are trade items and are identified with separate, unique GTINs (A, B, and C respectively). The 'level below the each' contains a single unit (i.e. unit of use) and could have a GTIN assigned (GTIN Y).

Hierarchy with a unit of use

A product can have various hierarchical packaging levels, in the example depicted below, 'each' contains a count of two (i.e., for illustration purposes, the count could mean two devices). In this case there are two single units, or 'units of use', per 'each'.

A product can have various hierarchical packaging levels. In the examples depicted below, the "each" contains more than one unit of use.

Figure 2-5 Hierarchy with a unit of use and an "each" containing more than one unit of use - Gloves

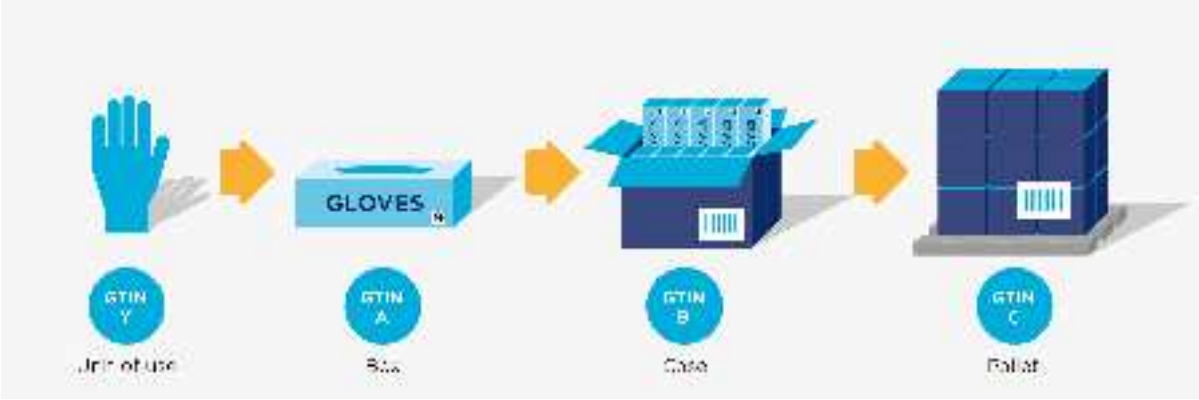

Figure 2-6 Hierarchy with a unit of use and an "each" containing more than one unit of use – glucose test strip example

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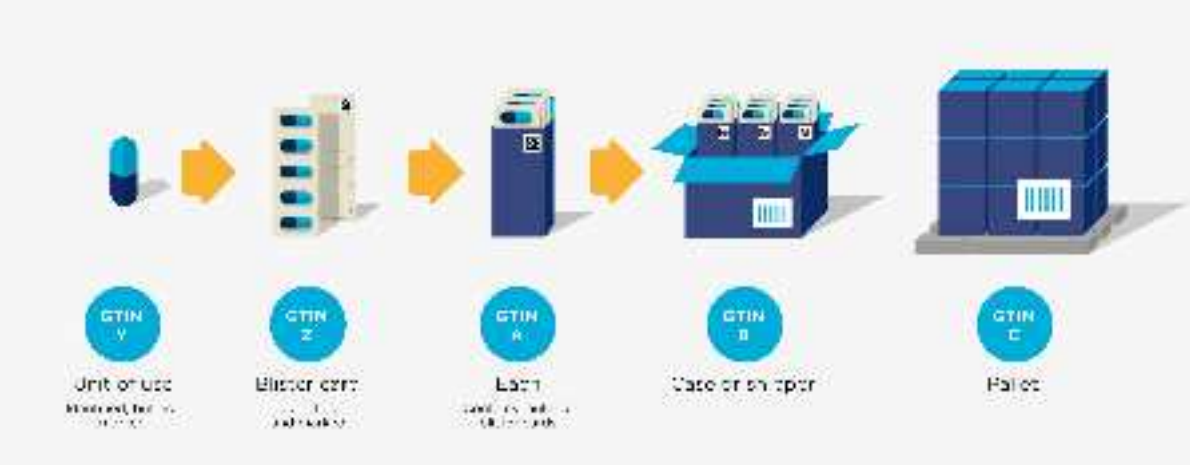
Figure 2-7 In this example the blister card is identified and marked with a single GTIN as the intended use is within a hospital or pharmacy setting and can be dispensed to multiple patients. The unit of use is identified with a GTIN but is not marked. The marking is at the discretion of the brand owner.



Hierarchy without a unit of use

Other products which contain a strip, tube, tray, pouch, foil pack, etc. or blister pack as depicted in the figures 2-8 and 2-9 may not have an assigned GTIN to the unit of use.

Figure 2-8: Hierarchy without an assigned unit of use below "each"

Note: Each pill or blister within the "each" is intended for one patient.

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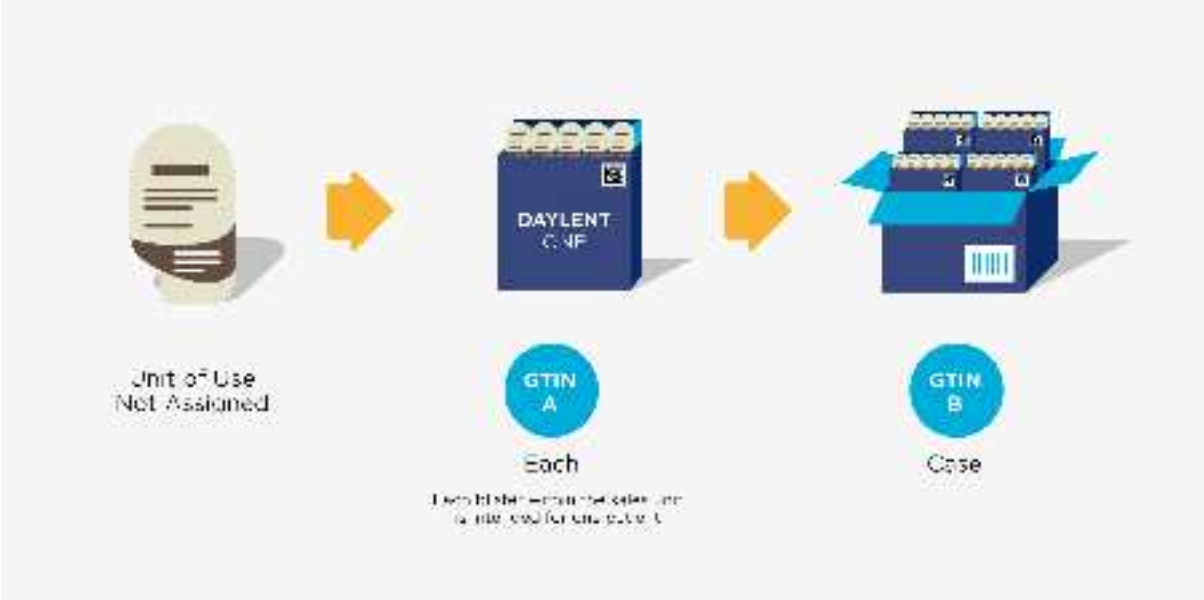
Figure 2-9 In this example, the blisters are intended for the single user obtaining the sales unit and therefore do not require a unit of use GTIN to be identified.

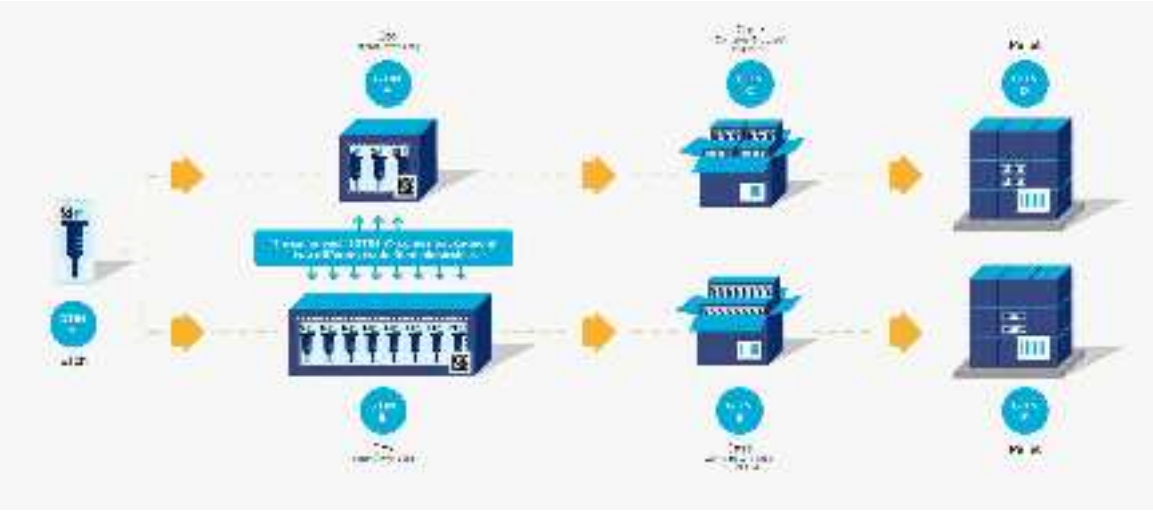


Note: Each pill or blister within the "each" is intended for one patient.

Unit of use with Multiple Hierarchies

In the example below, a unit of use device is available in two packaging configurations, a saleable item (i.e. the 'each') with three syringes and a saleable item with 8 syringes. In both cases the unit of use would have the same GTIN, if applicable, while the rest of the packaging hierarchy is assigned different and unique GTINs.

Figure 2-10 In this example, the unit of use (Each GTIN-Y) is packaged in two different trade item hierarchies but may or may not be marked



Additional information:

Solutions/liquids/creams/gels/powders/aerosols

- A GTIN is not expected to be allocated to the Unit of use for liquids, creams, gels, powders, and aerosols for example, unless required by regulation. GTINs assigned to these items are not marked using AIDC technology (e.g., barcodes).

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GTIN Assignment in a one to one (1:1) relationship between primary package and secondary packages

- 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 of medicine in a box or a transport wheelchair in a carton. In this situation the trade item primary package and secondary package may have different GTINs assigned when required by regulation. GTIN allocation and the marking of GTINs is made at the discretion of the brand owner.

Refer to the GS1 General Specifications for further information on trade item groupings.

Refer to section Healthcare Primary Packaging (Non-Retail Trade Items) of the GS1 General Specifications for more information.

2.2.4 Extra layers of packaging not constituting a new hierarchy level

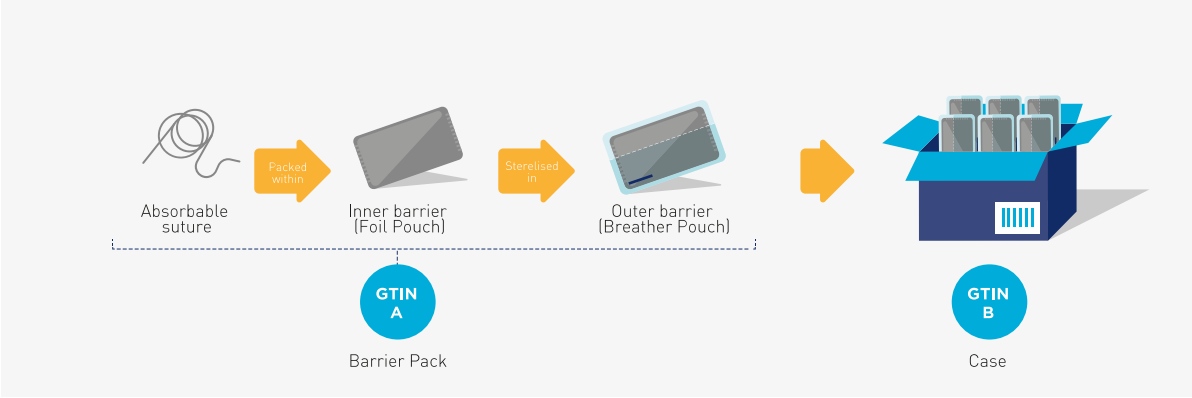
As a general rule, each distinct packaging level of a trade item requires a separate, unique GTIN.

However, additional layers of packaging that are generally not labelled and for which there is no need to retrieve predefined information and that are not priced, or ordered, or invoiced at any point in the supply chain do not constitute additional trade item hierarchy levels within GTIN allocation rules. This includes multiple levels of barrier and/or protective packaging as well as wraps, bundles, or similar configurations used solely to protect the product or to facilitate manufacturing or logistics handling.

Example: Barrier and/or protective packaging

The example below shows a typical product where the sterilisation requires two packaging levels (i.e. double barrier packaging or sealing inner through outer (SITO process)). Here, the foil pouch itself or the suture do not require a separate GTIN. Note that in this example, the breather pouch contains one foil pouch, which itself contains one suture – this is a precondition for allocating the same GTIN to this trade item. When the foil pouch contains more than one unit of use, this invokes the unit of use rule as per section 2.2.3 for the assignment of a GTIN.

Figure 2-11 Barrier packs (sterile packaging)



2.2.5 Declared net content

"Net content" is defined as the amount of the consumable product of the trade item contained in a package, as declared on the label, which may include net weight, volume, count, units.

Any change (increase or decrease) to the legally required declared net content that is printed on the pack, requires a GTIN change.

Hierarchy levels of GTIN assignment:

- The level at which the net content change occurs requires a new GTIN and all higher levels of the hierarchy impacted shall have a new GTIN.

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- The level at which the net content change occurs requires a new GTIN and all higher levels of the hierarchy impacted shall have a new GTIN. For example, if a catheter is currently sold in a box of 25 units and the manufacturer modifies the box to contain 50 units, the GTIN at the base package level must change. The GTIN should remain the same for the individual catheter. Please note that it is important to thoroughly communicate this change to healthcare providers and distributors to prevent confusion of supply chain errors.
- If the count at the base unit level, or the level below the "each" changes a new GTIN SHALL be assigned.

Example business scenarios that require GTIN change:

Figure 2-12 Change in declared net content - new GTIN

Note: 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.

Additional information:

Declared net content is what is used to develop shelf labelling and price per unit declared to the consumer. Declared net content is also important within clinical environments such as pharmacy. Accuracy of data and the ability to distinguish between products on the basis of net content is essential and failure to comply may result in a penalty or risk to patients/consumers.

2.2.6 Dimensional or gross weight change

A change of over 20% to a physical dimension, on any axis (e.g., height, width, depth), or gross weight, requires assignment of a new GTIN.

Note: Changes below 20% may require a new GTIN at the discretion of the brand owner.

Hierarchy levels of GTIN assignment:

- The GTIN assignment occurs at the trade item or base unit level.
- A unique GTIN is assigned at every existing level of the packaging hierarchy above the trade item/base unit level.

Example business scenarios that require GTIN change:

- The gross weight of a product increases by 50% from 0.34 kg (0.75 lb) to 0.51 kg (1.125 lb) due to a change in the packaging material.
- A case or pallet orientation (there is no change to the trade item count) may be changed such that one or more axis changes.
- In order to reduce the variety of folding box formats, a folding box with the dimensions of 47 x 18 x 127 mm is changed to 62 x 20 x 115 mm.

Figure 2-13 Dimension or gross weight change

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Note: The 20% change applies to each individual axis and not cube/volume.

Additional information:

- This part of the standard only applies to changes to the dimensions and the gross weight of a product. Any change to declared net content is governed by the rule on declared net content in section 2.2.5
- Cumulative changes in avoidance of the 20% threshold, without changing the GTIN, is an unacceptable practice. Trading partners should be notified about all dimensional changes. Cumulative changes might cause problems for trading partners and may obstruct the flow through of products.
- Refer to the GS1 Package Measurement Rules Standard for a consistent, repeatable process to determine measurements for a given product.

2.2.7 Pack/case quantity

This rule addresses predefined trade item groupings with predefined content. A change to the predefined number of trade items contained in a pack or case (i.e. trade item grouping) requires assignment of a new GTIN to the changed level and all impacted levels above. A change to the quantity of cases in a pre-defined pallet configuration requires assignment of a new GTIN.

Hierarchy levels of GTIN assignment:

- A unique GTIN is assigned at every existing level of the hierarchy including and above the lowest level that is changed.

Example business scenarios where a unique GTIN at the higher level packaging (e.g., pack, case) are required:

A case configuration changes from containing 8 trade items to containing 12 trade items, the case needs to be uniquely identified.

A case contains 5 inner pack boxes of 50. The box contents change from 50 to 60 per box. A new GTIN is required for the box and the case of boxes even if the number of boxes per case remains the same.

4 inner packs of 25 changed to 5 inner packs of 20 in a case requires new GTIN for both pack and case, a new GTIN is required for the inner pack and the case even if the number of units per case remains the same.

Additional information:

Refer to section 2.2.3 for assignment of GTINs to the each, level below the each, single unit and higher levels of packaging.

2.2.8 Pallet as a trade item

This rule applies when the pallet is a trade item and must be identified for ordering and invoicing purposes with a GTIN. In this scenario, GTIN allocation rules, including those for packaging hierarchy, apply.

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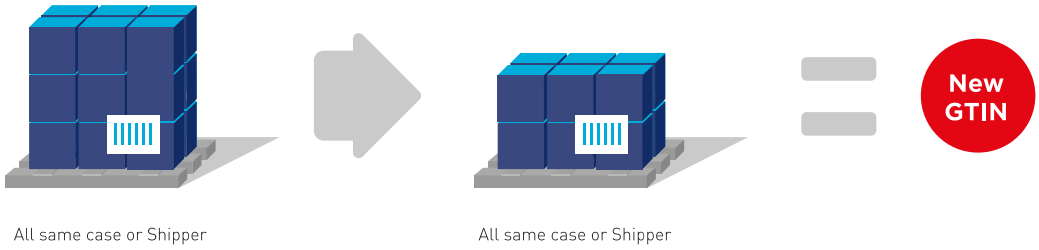
A change to the quantity of cases in a pre-defined pallet configuration requires assignment of a new GTIN. The pallet layout does not impact GTIN allocation of the pallet except where a dimensional change requires assignment of a new GTIN, (refer to section 2.2.6).

Hierarchy levels of GTIN assignment:

A unique GTIN is assigned to each pallet configuration that contains different quantity of cases when the pallet is an orderable item.

Example business scenarios that require GTIN change:

Figure 2-14 Additional or new pre-defined pallet configurations for ordering purposes require a different GTIN



A pallet configuration changes from containing 18 cases to containing 12 cases, the pallet needs to be uniquely identified.

Additional information:

Pallets require a GTIN only when they are a trade item (i.e. priced, ordered, or invoiced).

When a pallet is a logistics unit (e.g., shipment, transport, storage) it is identified with a Serial Shipping Container Code (SSCC).

Refer to the GS1 General Specifications for more information about logistics labelling and SSCCs.

2.2.9 Pre-defined assortment

A pre-defined assortment is defined as a pack of two or more different trade items that are combined and sold together as a single trade item not intended for a specific clinical or commercial purpose. Examples of a pre-defined assortment in healthcare are a first aid kit or a box of assorted sizes of adhesive bandages.

For trade items that are intended for a specific clinical or commercial purpose, refer to section 2.2.10 - Kits.

A change, addition or replacement of one or more trade items included in a pre-defined assortment, requires assignment of a new GTIN.

2.2.10 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. Kits can either consist of only finished goods, where all components are trade items identified with a GTIN, or both finished goods and unmarked goods, where at least one component is not a finished trade item and not identified with a GTIN.

There are two primary types of kits:

Made-to-Stock Kit: Kits that are a set assembly of components or trade items, in which the items in the kit are defined and marketed by the creator of the kit or the kitter.

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Note: In the case of the need for a short-term, temporary change in the assembly of components, the kitter should communicate the change to trading partners. There may be no need to change the GTIN in these unplanned, temporary circumstances. Consult local regulations.

Made-to-Order Kit: Kits that are a customizable assembly of components or trade items, which do not include set items defined by the creator of the kit or the kitter, but instead are customized based on the health care providers preferences typically from a set of available options. Kitter may choose to differentiate customized variations using production identifiers (e.g., lot, manufacturing date, etc.) instead of creating a large number of GTINs.

Note: These could also be called procedure packs or convenience kits. Jurisdictions may differ in their definition of kit.

Hierarchy levels of GTIN assignment for kits:

The creator of the kit or kitter is responsible for allocating the GTIN to the kit.

- The GTIN change occurs at the kit and all levels above.

The following GTIN change rules apply for Made-to-Stock Kits:

- Adding a kit component requires a new GTIN for Made-to-Stock Kits. See Figure 2-15 Addition of a component to a kit.
- Removal of a kit component requires a new GTIN for Made-to-Stock Kits. See Figure 2-16 Removal of a component from a kit.
- When kit components are identified by GTIN and/or brand owner item number, and that kit component is substituted, the kit GTIN Shall be changed. See Figure 2-17 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 2-18 Kit with unspecified components.

Example business scenarios that require GTIN change:

Figure 2-15 Addition of a component to a kit

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Figure 2-16 Removal of a component from a kit

Figure 2-17 Kit with specified components

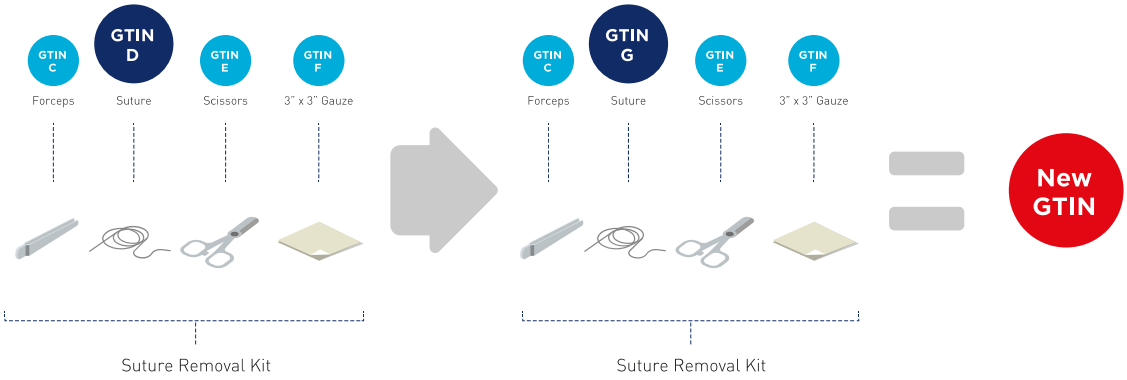
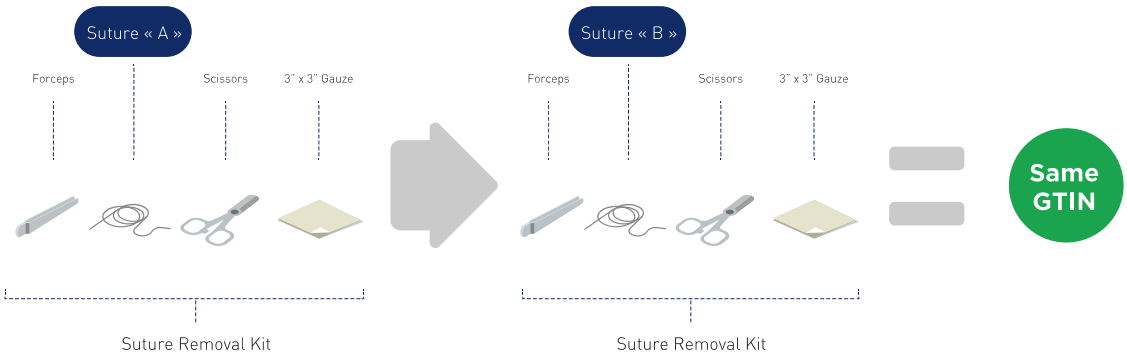


Figure 2-18 Kit with unspecified components



The following GTIN change rules apply for Made-to-Order Kits:

Adding or removing a kit component may require a new GTIN for Made-to-Order Kits at the discretion of the Kitter or when required per regulations. Kitters shall ensure identification reliably supports traceability and supply chain integrity when an addition or removal to Made to Order Kit components do not require a change to the GTIN. See Figure 2-19 Addition of a component to a kit and Figure 2-20 Removal of a component from a kit.

When kit components are identified by GTIN and/or brand owner item number, and that kit component is substituted, the kit GTIN may be changed at the discretion of the Kitter or when required per regulations. See Figure 2-21 Kit with specified components.

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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 2-22 Kit with unspecified components.

Example business scenarios that may require GTIN change:

Figure 2-19 Addition of a component to a kit

Figure 2-20 Removal of a component from a kit

Figure 2-21 Kit with specified components

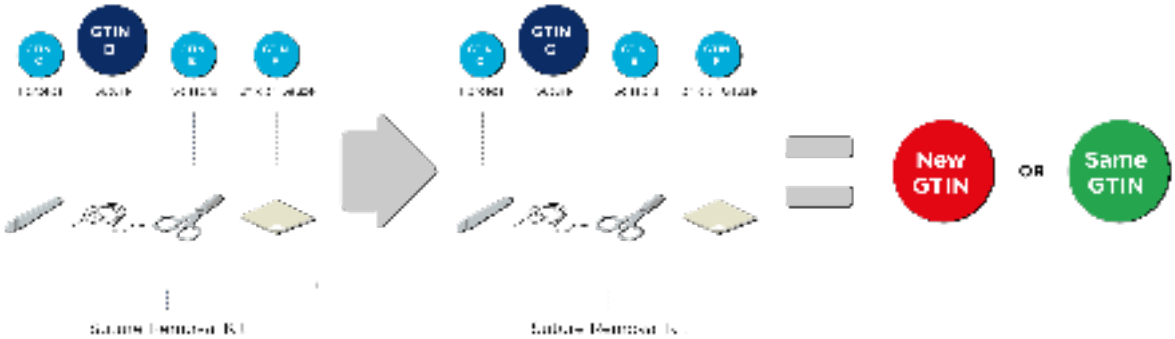

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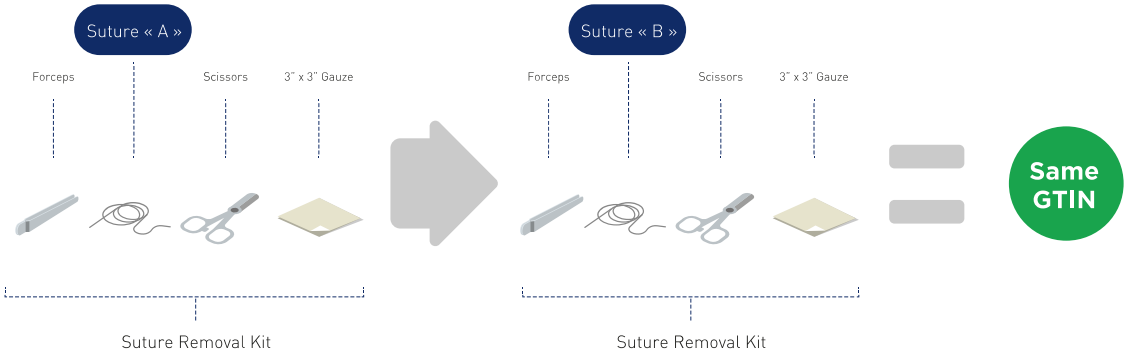
Figure 2-22 Kit with unspecified components



For trade items that are intended as a pre-defined assortment, refer to section 2.2.9 – Pre-defined assortment.

2.2.11 Price on pack

Price on pack is defined as when the brand owner includes pre-pricing as part of the package graphics. This rule does not apply to prices marked on a price ticket, sticker, hangtag, or anything that could be removed from the package or product.

Any addition, change or removal of a price marked directly on the product package (not recommended), requires assignment of a new GTIN.

Hierarchy levels of GTIN assignment:

- The GTIN change occurs at the base unit level.
- A unique GTIN is assigned at every existing level of the packaging hierarchy above the base unit level.

Example of business scenarios that require a GTIN change:

- The pre-printed price on a package changes from €3 to €2.
- A selling price of €8 is added to a product's packaging graphic.

Additional information:

Pre-pricing is discouraged as a trade practice as it introduces complexity for trade item file maintenance through the supply chain. In addition, there is a danger that the price declaration to the consumer (on the pack) is different to the price charged (price in retailer(s) or healthcare system). However, pre-pricing can be a mandatory requirement from the regulatory authorities.

2.2.12 Primary brand

The primary brand is the brand most recognisable by the care provider or patient, as determined by the brand owner, and can be expressed as a logo and/or words, registration mark or trademark.

A change to the primary brand that appears on the trade item, requires assignment of a new GTIN.

Hierarchy levels of GTIN assignment:

- The GTIN change occurs at the trade item, base unit level or level below the each if appropriate.

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- A unique GTIN is assigned at every existing level of the packaging hierarchy above the trade item/base unit level.

Example business scenarios that require GTIN change:

The company's primary brand name changed from "Healthcare Products Company" to "Leading Edge Healthcare Medical Products."

Additional information:

Co-branding: The act of applying a second brand (the 'co-brand') by a company under contractual agreement with the original brand owner.

- The company owning the co-brand is responsible for GTIN allocation.
- The co-brand being applied shall be constructed as the prominent brand on the package as viewed by the customer, thus ensuring relationship of the product with the co-brand, acknowledged as the 'Primary Brand' of the co-branded product.

Note: Contractual relationships may dictate that the 'Primary Brand' is not that of the co-brand, therefore the first and original brand shall remain prominent on the package. In this case, responsibility for GTIN allocation remains with the original brand owner

Distributed by: Products for which an agreement exists between the Brand Owner and the party identified on the label as the Distributor. The Brand Owner remains responsible for GTIN assignment and therefore no new GTIN is necessary when the Distributed by party identification is added to the label.

Note: The 'Distributed by' party identification must not include any registration marks or trademarks and must be made in plain text only.

Own Brand Label: Products wherein an agreement exists between the Original Manufacturer and the party identified on the label as the Brand Owner. The Brand Owner takes responsibility for GTIN assignment and therefore retains the alignment of brand to GTIN allocation.

2.3 Rules for product changes pertaining to Medical Devices

2.3.1 Configurable medical 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.

Hierarchy levels of GTIN assignment:

- A GTIN is assigned to the entire configurable medical device.

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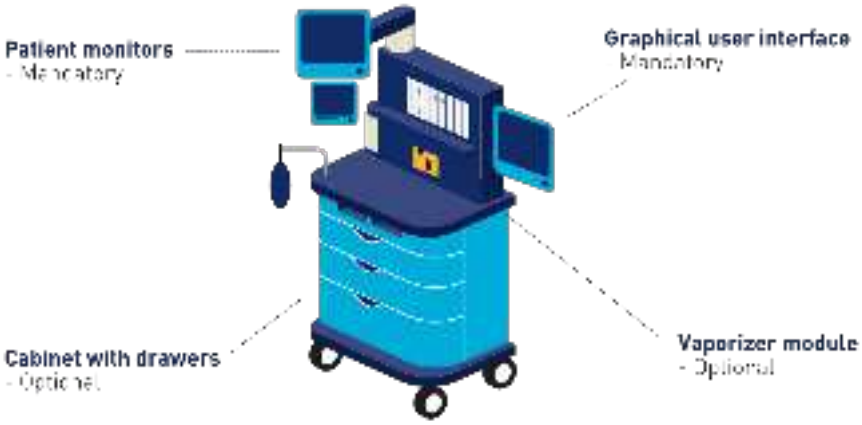
Figure 2-23 Example of a configurable medical device



- **OPTION 1**: Assign a GTIN to every final instance of the device. For example, each customised configuration has its own GTIN.
- **OPTION 2**:

1. A GTIN is allocated to the entire, configurable medical device system and may be used for a "System UDI" as described by regulators.
2. This GTIN may be allocated to defined groups of configurations, not per configuration within the group. A group of configurations is defined as the collection of possible configurations for a given product line as described in a regulatory file.
3. A production identifier(s) such as a Lot Number, Serial Number, Manufacturing Date, and/or Expiration Date is allocated to each individual device. A later change of a component, sub-systems or accessory of the system does not change the production identifier of the GTIN used for the system.
4. The GTIN should be put on the assembly that most likely does not get exchanged in its lifetime.
5. Each component, sub-system or accessory that is considered a medical device and a distributed or supplied unit needs a separate GTIN.
6. A new GTIN is required when the activities performed results in modifications to a previously marketed device intended for resale leads to a new medical device

Despite the fact that point 3 provides the general rule that the GTIN of a device already placed on the market or in use shall not be changed if there are later changes to the configuration of this device, it is necessary to make clear that for specific devices and under specific circumstances it might be necessary to be able to uniquely identify the changed device configurations in the field.

If a change of a device in the field would significantly change the safety, performance or the intended purpose (and these changes are not within the limits of the original configuration), those changed devices should be identifiable. To make the changed device identifiable a manufacturer should provide an upgrade kit[1] (which, itself, is considered a medical device) with a correspondent UDI which meets all UDI requirement (e.g. labelling, publication to UDI database(s), etc.). The UDI of the upgrade kit together with the original GTIN will be used to identify the changed device.

An alternative would be that a manufacturer might perform this change as new installation (comparable with a resale of a modified device as described in point 6) the new installed device would need to be marked with a corresponding new GTIN.

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(1)An "upgrade kit" (to be distinguished from the term "kit" defined in this document) is a term commonly used in industry to denote a packaged medical device used to upgrade an installed medical device (after this latter has been sold and first use or installation is completed). The "upgrade kit" includes all of the components or constituents required for the medical device upgrade and may also include installation instructions, service manuals and user manuals.

Appendix H: Examples of changes to configurable medical devices

This appendix is intended to describe if and how the GTIN is affected when changes are made to a device, which is already in commercial distribution.

Changes that make it necessary to identify the changed devices.

This section provides some examples where changes are made to devices which are in commercial distribution and the change does impact the safety, performance, intended use or indications for use for the device. In these situations, manufacturers must ensure that the changed devices are identifiable.

Example 1: Upgrade to system which impacts safety and/or performance

AMRI System 'Model A' is currently being manufactured and distributed to customers. The manufacturer develops new features and functionality (hardware or software or a combination of both) for that MRI system which are not covered by the original, approved specifications; the new features change the safety profile, the performance of the system or the intended uses. The manufacturer has determined that this results in a new model ("Model B") of the device. As the manufacturer decides to perform this modification as a new installation he will provide to the modified device a new GTIN. Alternatively, the manufacturer may provide an upgrade kit as a medical device with a separate GTIN and this GTIN together will be used for the identification of the changed device.

Example 2: Component change which impacts safety and/or performance

An X-Ray system with a 50 kV generator is changed to a 100 kV generator. These generator options are not specified for the original configuration(s), and the performance of the system is changed. The manufacturer has determined that this constitutes a new version/model of the system because the change in the generator of the X-ray system results in a new model/version of the system. If the manufacturer decides to perform this modification as a new installation he will provide to the modified device a new GTIN. Alternatively, the manufacturer may provide an upgrade kit as medical device with a separate GTIN and this GTIN together with original GTIN will be used for the identification of the changed device.

Example 3: New diagnostic feature, not previously approved, added to a device

A new diagnostic algorithm is introduced on a cardiac ultrasound system allowing new data calculations and imaging options. The algorithm introduces new indications for use and changes the performance of the system, and therefore the manufacturer has determined that this upgrade/model change does result in a new model/version of the cardiac ultrasound system according to their documented procedures for assessing device changes. As the manufacturer decides to perform this modification as a new installation he will provide to the modified device a new GTIN. Alternatively, the manufacturer may provide an upgrade kit as medical device with a separate GTIN and this GTIN together with original GTIN will be used for the identification of the changed device.

Examples for Changes where UDI remains unchanged

This section provides some examples where a change is made to a device which is in commercial distribution, however, the change does not require a special identification of the change device and does not impact the UDI.

Example 1: System component changed of an installed device; no change in safety or performance

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An installed CT system has an x-ray tube which has reached the end of its life and is replaced with a newer model tube by the original manufacturer without other changes to the device or its labelling. The manufacturer has determined that this does not constitute a new version/model of the system, according to their documented and approved description of the configuration (e.g. the safety profile, the performance of the system and the intended use are unchanged). As there is no significant change to the safety, performance, or the intended purpose, the GTIN remains unchanged.

Example 2: A customer-selectable option changed for an installed device

A CT system has an approved medical device registration/license, which includes several diagnostic algorithms. When a customer orders the device, they can choose which algorithms they would like activated based on their business model and budget. If a customer with an installed system subsequently purchases another diagnostic algorithm (which was approved for that system), due to changing business needs, that additional algorithm may be installed/activated and would not result in a new model/version of the system; the GTIN remains unchanged.

Example 3: Addition of an accessory for an installed device

The addition of an accessory that is covered by what is originally specified for the defined groups of configurations does not result in a new model/version of the system. Under this circumstance, the GTIN remains unchanged.

Form: This refers to the physical characteristics of a part:

Shape, size, dimensions, weight, material (sometimes included)

Basically: What it looks like and what it's made of.

Fit: This describes how a part interfaces or connects with other parts:

Mounting points, tolerances, alignment, clearance with surrounding components

Basically: Does it physically fit into the assembly correctly?

Function: This is about what the part actually does:

Its purpose or role, performance characteristics, how it behaves in operation

Basically: Does it work the same way and do the same job?

Exemptions:

- The addition of new mandatory components (that do not alter form, fit, or function affecting intended use) to a component selection list does not require a GTIN change.
- The replacement of an optional component with a functionally equivalent component does not require a new GTIN.
- The addition of new optional components not affecting form, fit, or function to those available for the configurable medical device does not require a GTIN change.

Example business scenarios that require GTIN change:

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.

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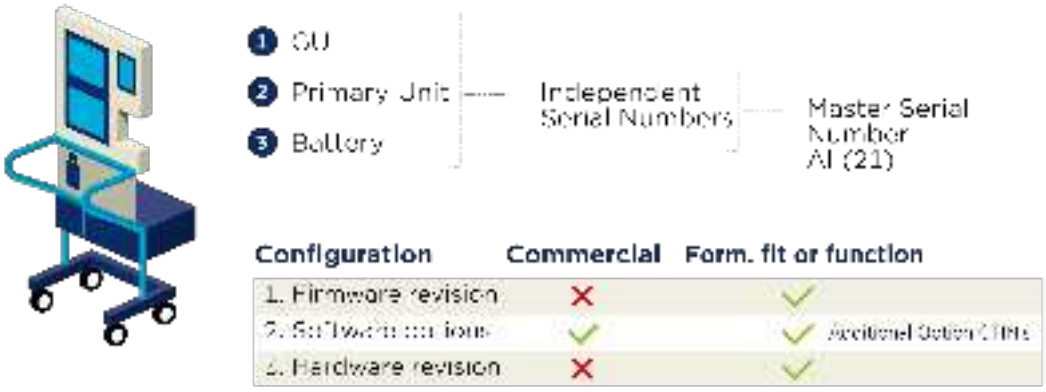
Figure 2-24 Example of a configurable medical device



*GUI = Graphical User Interface

- 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.
- 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.
- 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

Additional information:

When changes are made to a configurable medical device, a Global Individual Asset Identifier (GIAI) could be assigned by the device owner (this could be the manufacturer for leased or consigned devices or the end user for owned devices) and management of changes to the device would be handled via a change or maintenance record associated with the specific unit identified by a GIAI. For more information about the GIAI key refer to the Assets section of the GS1 General Specifications.

2.3.2 Software as a medical device

Medical device software is a software system developed for the purpose of being incorporated into a medical device or is intended itself for use as a medical device. 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 2.3.1.

- A **major** change in medical device software functionality affecting, form, fit, or function and intended use, requires a GTIN change.

Hierarchy levels of GTIN assignment:

- A GTIN is assigned to the medical device software which can be ordered, invoiced or shipped. Different licensing levels (e.g., limited number of users versus enterprise licenses) may require assignment of a different GTIN.

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Note: Examples of **major** changes include new or modified algorithms, database structures, architecture, new user interfaces, or new channels for interoperability.

Note: 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. Application identifier (8012) for Software version can be used when it is necessary to manage software versions. Software versioning is the process of assigning unique version numbers to unique states of computer software. The use of application identifier (8012) for Software version shall occur in combination with the GTIN. For more information regarding software versioning, refer to the GS1 General Specifications, section titled Software version: AI (8012).

Note: Once installed, medical device software SHALL remain identifiable with its assigned GTIN when separated from its packaging or physical documentation.

Additional information:

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. Medical device software that is distributed virtually such as via a download SHALL have the GTIN and any relevant application identifiers displayed within the software such as on the "About" screen.

2.3.3 Add or remove 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 relevance. It is a key principle of GTIN Allocation that the GTIN uniquely identifies the product and its packaging configuration.

A change to packaging to add a new, or remove an existing certification mark (e.g., European Certification Mark CE), that has significance to regulatory bodies, trading partners or to the end consumer, requires assignment of a new GTIN.

Hierarchy levels of GTIN assignment:

- The GTIN change occurs at the base unit level.
- A unique GTIN is assigned at every existing level of the packaging hierarchy above the base unit level.

Example business scenarios that require GTIN change:

Certification Marks that appear, or change, on product labels that impact global distribution channels due to country licence or registration, must be communicated between trading partners and therefore require a GTIN change.

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Figure 2-25 Inclusion of a Certification Mark – new GTIN

However, 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.

Additional information:

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 this scenario, if the external supply chain is unaffected.

Note: Be aware of target market, regulatory and customer requirements if this is an implemented practice.

2.3.4 Single-use devices/multiple devices never sold separately

Single use, medical devices packaged more than one to a package and multiple devices not commonly sold separately (e.g., number of cotton swabs, individually unpackaged, and contained in a single bag) may require a unique GTIN to be assigned.

Hierarchy levels of GTIN assignment:

A GTIN is assigned at the 'each' level.

Higher levels of packaging are assigned a separate, unique GTIN at each level if these levels are considered trade items. See section 2.2.7 for more information.

Level below the each, down to the single unit (i.e., unit of use) may have a GTIN assigned. However, it may or may not be marked on those levels.

Example business scenarios that require a new GTIN:

- Examples of multiple devices not commonly sold separately that may require assignment of a GTIN such as high quantity screws/pins, gloves/gowns, swabs, tape, number of cotton swabs, individually unpackaged, and contained in a single bag and examples of single-use non-sterile devices include gauze, swab, tissue, etc.

Additional information:

- For information on multi-use devices see section 2.3.5

2.3.5 Multi-use devices

A GTIN should be allocated to a single unit of a multi-use device.

Hierarchy levels of GTIN assignment:

- The GTIN is assigned at the single unit.

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- A separate GTIN is assigned at each packaging level of the hierarchy which may be priced, ordered, or invoiced.

Example business scenario:

A non-disposable blood pressure cuff is one example of a multi-use device.

Additional information:

GTINs, assigned to the level below the each (e.g. single unit, or unit of use), may be marked using AIDC technology (e.g., barcodes). Depending on the type of device there may be regulatory requirements for permanent or direct part marking (DPM).

2.3.6 Declared formulation or functionality of a Medical Device

"Functionality" is defined as the particular use or set of uses for which the Medical Device is designed. "Formulation" is defined as a list of the ingredients or components used to create the Medical Device.

A change to the formulation or functionality that affects the legally required declared information of a product only requires the assignment of a new GTIN if the brand owner expects the customer or supply chain partner to distinguish the difference between the products prior and after the change.

An example business scenario that requires a new GTIN

Change that affects the intended purpose / use of a product.

If the change does not change the use of the product or the effect to the patient and there is no regulatory requirement, changing the GTIN is not required.

Functionality:

A change in form, fit, or function of the Medical Device affecting intended use may require a change to the GTIN.

2.4 Rules for product changes pertaining to Pharmaceutical products

2.4.1 Declared formulation of a Pharmaceutical product

"Formulation" is defined as a list of the ingredients used to create a Pharmaceutical product.

A change to the formulation that affects the legally required declared information on the packaging of a product only requires the assignment of a new GTIN if the brand owner expects the customer or supply chain partner to distinguish the difference between the products prior and after the change.

Additional Information

A formulation change may require a regulatory filing and may result in a change of the declared information on the packaging.

Example business scenarios that require a new GTIN

- Change to an active ingredient in a product
- Change of the strength of the product (how much of active ingredient is present in the product)
- Change to the physical appearance (tablet, powder, sterile liquid) of the product as presented to the customer

2.5 Other rules pertaining to Medical Devices and Pharmaceutical products

This section includes specific and unique rules that do not fall under the previously mentioned categories.

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2.5.1 Time critical or promotional product

Promotions are normally short-term modifications to the way the item is presented.

A change to a product that is being promoted (including packaging changes) for a specific event or date, impacting the required handling in the supply chain to ensure the trade item is available for sale during a specified time period, requires assignment of a new GTIN.

Hierarchy levels of GTIN assignment:

No GTIN change is required at the base unit level if the content of the product remains unchanged.

Existing levels of the packaging hierarchy above the base unit require a unique GTIN to be assigned for time critical promotions.

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.

Example business scenarios where a unique GTIN at higher level packaging (e.g., pack, case, pallet) are required:

A free trial item (not identified with its own GTIN) is attached to an existing item for a promotional period, the declared net content of the original item is unchanged and packaging dimensions, and the gross weight of the product are NOT changed by more than 20%.

Example business scenarios that do not require GTIN change:

Promotion: buy 2, get 1 free

The graphics on bandages rotate quarterly. The graphics have no seasonal or time critical relevancy and are considered flow-through products.

Additional information:

For time critical or promotional products, the GTIN for the trade item/base unit level does not need to be changed, but for tracking in the supply chain, higher levels of packaging need to be uniquely identified.Local, national or regional regulations may require more frequent GTIN changes. Such regulations have precedence over the rules provided within the healthcare GTIN Allocation Rules.

2.5.2 Patient specific product

In the case where a product is prepared specifically for an individual patient (for example in a hospital pharmacy or by an implant manufacturer) the party preparing or manufacturing the product is responsible for assigning the GTIN. A patient specific product should be identified so that it is uniquely attributed to the individual patient and/or a specific production instance.

Hierarchy levels of GTIN assignment:

A GTIN is assigned to the base product defined by key properties like ingredients, basic formula, indications, fundamental design etc. The patient specific product is then identified by the GTIN for the base product and a batch/lot and/or serial number. A new GTIN shall be assigned when any of the key properties of the base product changes.

Note: At the discretion of the brand owner a new GTIN may be assigned to each patient specific product.

Example business scenario:

A hospital pharmacy prepares a specific product designed for a specific patient. In some cases, this is referred to a 'personalised medicine".

See section 2.3.1 for example of configurable medical devices.

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3 Clinical Trials

A clinical trial is conducted to investigate the efficacy and safety of treatments, interventions or tests – in preventing, managing or detecting disease or other medical conditions. Clinical trials can compare a new treatment to existing, test different combinations of existing treatments, or even look at other lifestyle factors and their impact on the patient's well-being.

Clinical trials have product identification complexities not seen today in the commercial healthcare supply chain. The uniqueness of an investigational product, which in many cases is only for one patient means this has a need to be identified to the instance of the product. In blinded trials the blinded parties should not be able to see from the labelling whether the investigational product is a test article, comparator or placebo. Application of GS1 standards for clinical trials must take these complexities and industry needs into account.

In the event where the presentation of product changes, please refer to the Clinical Trial application standard.

For specific information on GTIN Allocation Rules refer to section 7 of the Identification of Investigational Products in Clinical Trials Application Standard.

For general information refer to the Identification of Investigational Products in Clinical Trials Application Standard.

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4 Additional GTIN information

Global Trade Item Number

Global Trade Item Numbers (GTINs) can be used by a company to uniquely identify all of its trade items. GS1 defines trade items as any item (product or service) upon which there is a need to retrieve predefined information and that may be priced, ordered, or invoiced at any point in any supply chain. For more information on GTIN refer to the GS1 General Specifications.

Structure of a GTIN

Companies can license a GS1 Company Prefix from a GS1 Member Organization that comes with full documentation on how to allocate GTINs to their products.

GTINs 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.

GS1 Company Prefix

GS1 Company Prefixes are licensed by GS1 Member Organisations to a user company to entitle that user company to create any of the GS1 identification keys, such as GTIN, SSCC, or GIAI.

Note: While the GS1 Company Prefix can be used to determine which GS1 Member organisation allocated the prefix, it cannot be used to determine where an item was produced or distributed.

U.P.C. Company Prefix

A U.P.C. Company Prefix is derived from a GS1 Company Prefix that starts with zero (‘0’) by removing that leading zero. A U.P.C. Company Prefix SHALL only be used to construct 12-digit trade item identifiers (e.g. GTIN-12). When a leading zero is added to a U.P.C. Company Prefix it becomes a GS1 Company Prefix that may be used to issue all other GS1 identification keys.

Note: For example, the 6-digit U.P.C. Company Prefix 614141 is derived from the 7-digit GS1 Company Prefix 0614141.

Item reference

The item reference is a component of the Global Trade Item Number (GTIN) assigned by the organisation to whom the GS1 Company Prefix or U.P.C. Company Prefix has been licensed 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 the item references is sequentially, e.g. 000, 001, 002, 003, etc.

Check digit

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

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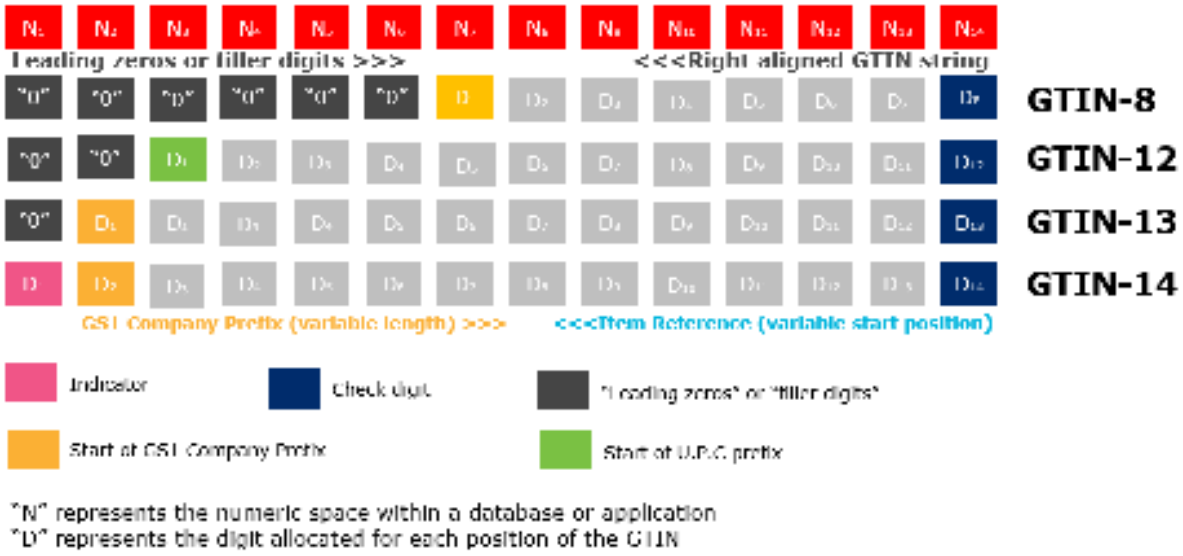
The figure below shows the four GTIN structures and how they should be stored in a database. The GTINs should be right justified and zero filled on the left.



Note 1: When any of these GTINs are encoded in a data carrier that must encode a fixed-length data string of 14-digits, the GTINs when less than 14-digits in length must be prefixed by padded zeros that simply act as filler digits. Adding fill zeros does not change a GTIN-8, 12 or 13 into a GTIN-14. However, the "filler" zeros are not encoded in EAN-8, U.P.C-A or EAN-13 barcodes.

Note: 2: The 14-digit GTIN format is used in business transactions, especially for eCommerce (e.g., electronic orders, invoices, price catalogues, etc.) and in the Global Data Synchronisation Network (GDSN).

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. The simplest way to allocate the indicator is sequentially that is 1, 2, 3… to each trade item grouping.

A uniform grouping of trade items is an orderable grouping of identical trade items. The brand owner 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 digit value of 1 to 8. These GTIN-14s 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. Due to the value options of 1 to 8, eight, separate, unique GTIN-14s can be created from a single GTIN-13 or GTIN-12.

The indicator digits 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. The indicator digit assigned as required by the company that constructs the GTIN.

Note 1: The indicator value 9 is reserved for variable measure items. **Variable measure**: If the measure of items contained in a case, is not pre-defined then the trade item is of variable measure. Some of the attributes related to this variable measure trade item, such as the count of units contained and the weight for example, are not pre-defined but will be known only when the product is manufactured. It needs to be decided upfront if an item is a fixed measure one with pre-defined essential attributes or a variable measure one, where one measure such as the count of units contained, is not pre-defined but is specific to each instance. In such cases a GTIN-14 with Indicator 9 and Application Identifier (30) may be used. For more information refer to the Variable count of items: AI (30) section of the GS1

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General Specifications. Additional information on variable measure is found is the following sections of the GS1 General Specifications: Variable measure trade items scanned in general distribution and Variable measure trade items scanned at retail Point of Sale.

Note 2: Some scanners at retail point-of-sale may not be capable of reading and interpreting barcode symbologies other than EAN/UPC, which cannot encode a GTIN-14.

Note 3: See GS1 General Specifications GTIN sections for further information.

Note 4: For more information on how to construct a GTIN refer to How to create a GTIN on the GS1 website or contact your local GS1 Member Organisation.

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5 Glossary of terms

For latest definition of terms refer to www.gs1.org/glossary.

Term	Acronym /Abbreviation	Definition
barrier pack		A type of package shielding the contents from contact with external substances or other external influences. Depending on the material and the packaging process it may provide protection against e.g. light, moisture or microorganisms, i.e. preserve the sterility of the contents.
blister pack		A type of package in which the material (frequently plastic or metal foil) is formed to one or more blisters, each usually containing one unit of the product. The open bases of the blister cells are usually sealed by affixing a layer of plastic or metal foil or of paper which will be perforated when a cell is accessed, thus making the manipulation obvious (tamper evidence).
brand owner		The organisation that owns the specifications of a trade item, regardless of where and by whom it is manufactured. The brand owner is normally responsible for the management of the Global Trade Item Number (GTIN).
breather packaging/pouch		A package of layer of fibrous material. Breather package for surgical elements such as sutures or suture-needle assemblies having a layer of fibrous material and a layer of plastic material forming a pocket between.
check digit		Numeric character calculated from data and appended as part of the data string to ensure that the data is correctly composed and transmitted.
Co-branding		The act of applying an additional recognisable brand (secondary brand), logo, trademark or registration mark to a product label or package, where it co-exists with the primary brand. This would normally be performed under contractual agreement with the original brand owner.
direct part marking	DPM	Direct part marking refers to the process of marking a symbol on an item using an intrusive or non-intrusive method.
dosage		The quantity per application and the frequency of application of a drug.
each/base unit		In a packaging hierarchy of trade items, the Base Unit or Each denotes the retail consumer trade item level. The term each refers to the lowest traded packaging level. This level might contain more than one single unit/unit of use.
equivalent		A product which can be substituted for the trade item based on supplier- defined functional equivalence to the trade item.
formulation		Definition of the combination of different chemical substances, including the active ingredients, constituting a final medicinal product.
Form, fit or function		A change in the product's specifications or design that changes the intended purpose / use and needs to be communicated to the customer.
Global Trade Item Number	GTIN	The GS1 identification key used to identify trade items. The key comprises a GS1 Company Prefix, an item reference and check digit.
GS1 Application Identifier	AI	The field of two or more digits at the beginning of an element string that uniquely defines its format and meaning.
GS1 Company Prefix	GCP	A unique string of four to twelve digits used to issue GS1 identification keys. The first digits are a valid GS1 Prefix and the length must be at least one longer than the length of the GS1 Prefix. The GS1 Company Prefix is issued by a GS1 Member Organisation. As the GS1 Company Prefix varies in length, the issuance of a GS1 Company Prefix excludes all longer strings that start with the same digits from being issued as GS1 Company Prefixes. See also U.P.C Company Prefix.
GS1 element string		A syntax for expressing GS1 identifier keys and attributes in a format using GS1 Application Identifiers and GS1 Application Identifier data fields.
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.

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Term	Acronym /Abbreviation	Definition
GS1 Global Office	GS1 GO	GS1 is a neutral, not-for-profit organisation that provides global standards for efficient business communication. The Global Office, located in Brussels (Belgium) and Ewing, NJ (USA) is the guardian, and provides an open, user driven, forum for ongoing maintenance and development, of the GS1 standards, guidelines and statutes.
GS1 Member Organisation	GS1 MO	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 user companies 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 sum of all the artefacts created by the GS1 community through GS1's community development processes, including GS1 standards, GS1 guidelines, GS1 solutions, and GS1 data services.
Global Data Synchronisation Network	GDSN	The GS1 Global Data Synchronisation Network® (GDSN®) is a network of interoperable data pools enabling collaborating users to securely synchronise master data based on GS1 standards.
Graphic user interface	GUI	Graphical user interface - is a form of user interface that allows users to interact with electronic devices through graphical icons and audio indicator such as primary notation, instead of text-based user interfaces, typed command labels or text navigation.
healthcare primary packaging		The first level of packaging for the product marked with an AIDC data carrier either on the packaging or on a label affixed to the packaging. For non-sterile packaging, the first level of packaging can be the packaging in direct contact with the product. For sterile packaging, the first level of packaging can be any combination of the sterile packaging system, may consist of a single item or group of items for a single therapy such as a kit. For packaging configurations that include a retail consumer trade item, primary packaging is a packaging level below the retail consumer trade item.
indicator		A digit from 1 to 9 in the leftmost position of the GTIN-14.
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 different regulated healthcare items assembled for use in a single therapy.
Kitter		The brand owner 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.
Level below the each		The lowest hierarchy level of trade items within the GS1 System is traditionally referred to as the "each" level. The "each" level trade item may contain more than one unit of use. In this case there may be the need to identify levels below the 'each' down to the single unit or unit of use. In the Healthcare industry, there can be a "smaller" or "lower" unit, which will be scanned at the "Healthcare Point of Care, commonly referred to as the "Level Below the Each"
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.
Pharmaceutical product		A pharmaceutical is any kind of drug used for medicinal purposes, like cough syrup or sleeping pills.
Primary brand		The primary brand is the brand most recognisable by the care provider or patient, as determined by the brand owner, and can be expressed as a logo, registration mark or trademark.
regulated healthcare trade item		Pharmaceuticals or medical devices that are sold or dispensed in a controlled environment (e.g., retail pharmacy, hospital pharmacy).

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Term	Acronym /Abbreviation	Definition
seal inner through outer	SITO	A type of barrier package consisting of two layers. In a special production process the inner layer (frequently a foil pouch) initially stays open for sterilisation of the contents and then is sealed through the outer layer, which was closed before and stays intact throughout.
secondary package		The layer of packaging surrounding the primary package. May be used for purpose of presentation and branding or for additional mechanical protection the primary package might not be able to provide. May contain one or more primary packages.
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 attached to each other, but are easily separated through a perforation would be included.
strength		Amount of active ingredient(s) in a drug.
trade item		Any item (product or service) upon which there is a need to retrieve predefined information and that may be priced, or ordered, or invoiced at any point in any supply chain
Unique Device Identifier – Device Identifier	UDI-DI	A unique identifier specific to a medical device trade item represented by a Global Trade Item Number (GTIN).
Unique Device Identifier – Production Identifier	UDI-PI	A numeric or alphanumeric code that identifies the unit of device production. The different types of UDI-PIs include serial number, lot number, software identification and manufacturing or expiry date or both types of date.
Unique Device Identifier	UDI	A series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard. It allows the unambiguous identification of a specific medical device on the market. The UDI is comprised of the UDI-DI and the UDI-PI. The word 'Unique' does not imply serialisation of individual production units.
unit of use	UoU	Refers to an individual unit package that is prescribed for or administered to a patient regardless whether it is packaged individually or, on the contrary, the smallest package contains more than one unit. May coincide with the single unit and the base unit.
U.P.C. Company Prefix		A GS1 Company Prefix starting with a zero ('0') becomes a U.P.C. Company Prefix by removing the leading zero. A U.P.C. Company Prefix is used to issue and allocate GTIN-12.

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