# Guide

# DATA MODEL GDSN HEALTHCARE - ITALY

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# Index

Guide to Data Model GDSN Healthcare - Italy

# 1 Executive summary

The healthcare sector has long been focusing on the subject of the efficiency and safety of product procurement processes and logistics management. Companies and local structures almost anywhere in Italy have to face this challenge and have tried to identify solutions that would radically affect not only the company internal management processes but also the reference models of distributed logistics for drugs and medical devices.

In this new scenario, one of the emerging needs is the use of a Data Model to describe products - as homogeneous as possible and shared among all the players along the supply chain.

After contacting the organizations involved in this kind of projects in Italy, it was recognized the importance of identifying a extra-regional area for the development of a solution that could take into consideration the nature of the offer (national/international) and the regulatory constraints (national/European/global). A work group was founded with the purpose of sharing a set of information necessary to the Data Model for medical devices.

The activities of the Work Group led to the drafting of this Guide which main purpose is to be a support tool for the correct understanding and use of agreed Data Model.

The Data Model GDSN HealthCare - Italy represents the implementation in national cases of tools developed in the GDSN Healthcare project of the International GS1 Healthcare Work Group.

The GS1 GDSN (Global Data Synchronization Network) documents (BMS - Business Message Standard) remain the fundamental reference for the application/implementation of the master alignment system and the sharing of standard information.

A special thanks goes to the members of the "Standard GS1 per l'identificazione e l'allineamento anagrafico in Sanità" Work Group. Observations and suggestions were fundamental in the drafting of this Guide.

The Work Group consists of leading companies in the production and distribution of medical devices and companies and agencies playing here as product final users. This represents a highly-representative scenario of the Italian industrial sector:


ALCON ITALIA

AOU OSPEDALI RIUNITI DI TRIESTE

ARESS PIEMONTE

ARSS VENETO

ARTSANA

ASFO TRIVENETO

ASO MOLINETTE TORINO

ASSOBIOMEDICA

AUSL CESENA

BAXTER

BBRAUN ITALIA

BOMI GROUP

D-GROUP

DELTA BIOLOGICALS

EBNEURO

ESTAV CENTRO TOSCANA

INGEGNERIA BIOMEDICA SANTA LUCIA

INSTRUMENTATION LABORATORY

JOHNSON & JOHNSON MEDICAL

MEDILINE

MEDTRONIC ITALIA

MINISTERO DELLA SALUTE

MOLNLYCHE HEALTH CARE

MORETTI

REGIONE EMILIA ROMAGNA

REGIONE FRIULI VENEZIA GIULIA

STUDIO GENAS

SAN MATTEO PAVIA

SORIN GROUP

## 2 Introduction

Every company has at least one archive containing all master data related to the products it manufactures, sells or buys. But when the company needs to modify any piece of information in its database or add a new element, another archive might no longer be aligned. The misalignment of product master data between supplier and final user along the logistics supply chain represents the main cause of many errors and expensive disputes between trading partners in the various processes of order/deliver/pay cycle they are involved in.

GS1 Italy|Indicod-Ecr GDSN Electronic Catalogue wants to eliminate these problems, reducing management costs and maximizing the efficiency of communications along the supply chain.

In brief, the Global Data Synchronization Network (GDSN) counts on a Data Pool Network and a Global Registry which allow several companies anywhere in the world to synchronically share standard data with their commercial partners, guaranteeing that data shared between parties are unique and conform to global standards.

Medical devices (in this case) - called Trade Item - are identified thanks to a GS1 Key called GTIN (Global Trade Item Number) whereas companies and places along the supply chain are identified by a Global Location Number (GLN). A combination of GTIN, GLN and Target Market (the geographic area where a particular product master data is valid) permits to share the information on the device, guaranteeing its uniqueness within the network.

GDSN permits to commercial partners to share always up-to-date information and to remain synchronized after every change. When a supplier and a client know they are consulting and seeing the same valid and accurate data, it becomes easier, faster and cheaper for commercial partners and their logistics supply chains to operate efficiently. GDSN provides the organizations with a unique access and knowledge point ("a single point of truth") of all product information.

The steps that allow commercial partners to synchronize product data are few and easy:

- *Data input:* the manufacturer uploads in the data pool the information related to its product master data. In this operation, data are not visible to commercial partners.
- *Registration:* a subset of uploaded data is automatically sent to the Global Registry which guarantees its uniqueness within the network and its retrieval to partners requesting for synchronization.
- *Subscription (Synchronization Request):* through his own data pool (which might differ from manufacturer's), the commercial partner requests information to the manufacturer activating a subscription characterized by one or more combined parameters chosen among GTIN, GLN, TG or GPC codes (Product or Company Code, Target Market or Product Classification Codes).
- *Publication:* the manufacturer may decide which (GLN) buyers/users or which Target Market the information are published to. The manufacturer's data pool will carry out the matching between the partner requests and the publications, forwarding the final user data through their data pool.
- *Confirmation:* the commercial partner may send a feedback message to the manufacturer through their own data pool – the partner may accept to receive, deny (and therefore ending any further synchronization with that/those code/s) or send comments regarding the received information.

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From a technological point of view, all the information are shared by using **XML** files built according to the standards developed and maintained by GS1 through a **AS2** connection protocol for communication between the company and the data pool to which it refers.
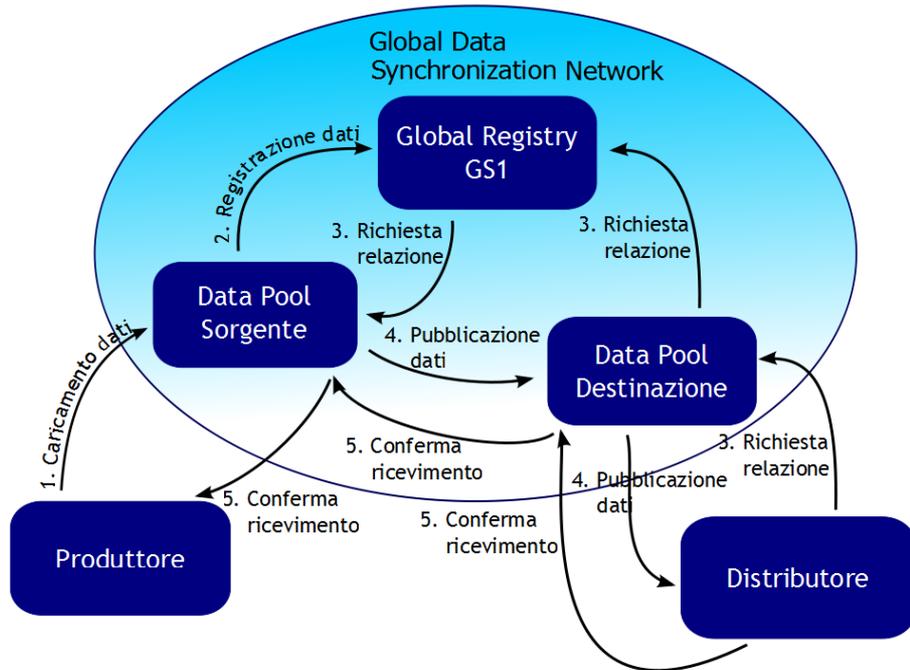


*[1. Data Uploading; 2. Data Registration; 3. Relation Request; 4. Data Publication; 5. Receipt Confirmation.*
*Manufacturer, Data Pool Source, Global Registry GS1, Final Data Pool, Distributor]*

Moreover different methods to communicate data to a data pool are available so that a manufacturer is not obligated to use XML for the uploading and management of master data. These methods, offered by the provider, might consist in the direct drawing up of sheets on a web portal or the uploading of Excel tables.

In Italy, GS1 Italy|Indicod-Ecr provides the E-Catalogue using the infrastructure of one of the most popular access providers: SA2 Worldsync – one of the 28 Data Pool Certified in the world. GS1 Italy|Indicod-Ecr is responsible for all the partnership activities with Italian companies (marketing, administration and technical support), offering the necessary support to the user in the understanding and use of the E-Catalogue.

# 3   DATA MODEL GDSN HEALTHCARE - ITALY

This chapter will describe all the attributes that constitute the set of information approved by the member of the "Standard GS1 per l'identificazione e l'allineamento anagrafico in Sanità" Work Group for the description of medical devices along the logistics supply chain, from the manufacturer to the final user of the product.

The attributes listed below have been divided into functional categories to facilitate the users in the drawing up of fields. Therefore, they might not respect the order followed by the official GS1 documentation. For any further information, please refer to the official GS1 documentation and contact GS1 Italy|Indicod-Ecr project managers.

## 3.1   Definitions

The structure of the attributes developed by the GS1 GDSN standard are divided into:

- CORE attribute: attributes which definition is general and transversal to all products belong to the "Core" group ("Neutral"). Core attributes are common to all the geographies (Target Markets, countries). Core attributes CANNOT depend on particular relationships between commercial partners.
- EXTENSION attribute: attributes developed for a specific product sector or a particular geographic area belong to the "Extension" group. Together with the "Core" group, in the Data Model GDSN Healthcare – Italy we find some specific attributes for the product sector developed in accordance to GS1 GDSN standard "Extension Healthcare".

Each attribute operates in a class of attributes.
For each class and attribute a status is defined:
- M: MANDATORY → The data field must be filled in in accordance with the Data Model specifics.
- O: OPTIONAL → the data field can be used, if necessary, to meet the user's needs. Some fields, even if theoretically optional, might become essential from an operative point of view.
- D: DEPENDANT → the data field depends on its previous one. If the parent data field contains information in the Data Set, therefore the dependant field must be completed.

If an attribute class is defined as MANDATORY, all the attribute fields defined as mandatory in the class must be filled in. The other fields defined as optional can be filled in or not, in accordance to the needs of the different users.

Moreover, in the definition of each attribute there are several characteristics that are necessary to describe its structure and its use:

- MULTEPLICITY → this characteristic identifies the possibility to repeat an attribute in the same set of information of a trade item

- HIERARCHY LEVEL of the package to which the attribute can be associated to → not all the attributes can be associated to all package levels that can be described through the Data Model GDSN. Those defined by the GS1 GDSN standard are:
  - MX: Mixed Module
  - PL: Pallet
  - DS: Display or Shipper (1/2 pallet, 1/4 pallet)
  - CA: Case
  - PK (Pack/Innerpack): inner pack between case and EA (each) that might or might not be codified through a barcode
  - AP (Assorted Pack/Setpack): inner pack between case and EA (Each) that might or might not be codified through a barcode
  - EA (Each): trade unit, single reference identified through a GTIN

  A characteristic indicates to which defined package levels the attribute can be associated to. The indication "ALL" means that the attribute can be described for all the defined package levels. Please refer to "GDSN Trade Item – Implementation Guide, Issue 13, Aug 2010" for more information on the different package levels defined.

- HIERARCHY UNIQUE VALUE → this characteristic indicates if in the description of the different package level, the attribute remains the same or changes in accordance to the package level (the GTIN level is not the same in the hierarchy, whereas the GNL value of the information publisher remains the same).

- TYPE OF FIELD → Indicates the type of data field
  - CODELIST (EnumeratedList, Multi Measurement Value, N): the values are chosen from defined lists.
  - N: Numeric Value
  - AN: Alphanumeric value
  - MULTI-SHORT DESCRIPTION, LONG TEXT DESCRIPTION: this field is a text field
  - BOOLEAN: this field is characterized by a True/False, Yes/No value
  - DATE: this field indicates a date
  - DATETIME: this information field indicates date and time

- DIMENSION → Indicates dimension and structure of the information field:
  - The attribute field can have fixed or variable length. The characteristic indicates the number of digits in case of fixed-length field (14) while it indicates the maximum number of digits in case of variable-length field (.. 35).
  - YYYY-MM-DD: the field indicates the date structured in 4 digit for the year, 2 digits for the month, and 2 digits for the day (Year(4) – Month(2) – Day (2))
  - YYYY-MM-DDTHH:MM:SS: the field indicates the date structured in 4 digit for the year, 2 digits for the month and 2 digits for the day, 2 digits for the minute, and 2 digits for the second (Year(4) – Month(2) – Day (2) – Minute (2) – Second (2))
  - N/A = Codelist value

Please notice that the type and dimension of the fields are defined by the international GS1 standards.

## 3.2 Description

### 3.2.1 "Core" Functional Category: IDENTIFICATION

Within this functional category fall all the attributes for the identification of the Trade Item.

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **Hierarchy Level (of package)** | **tradeItemUnitDescriptor** | Identifies the hierarchical configuration of the trade item |

The described trade item is defined within a hierarchy configuration of the package. The attribute is mandatory and its meaning is described by the codelist "Trade Item Unit indicator" the user chooses the appropriate one from. For more information about the package hierarchy, please refer to the document: GDSN Trade Item – Implementation Guide, Issue 13, Aug – 2010.

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **GTIN** | **globalTradeItemNumber** | The Global Trade Item Number (GTIN) is used for the unique identification of trade items worldwide. 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, ordered, or invoiced at any point in any supply chain. |

The GTIN – Global Trade Item Number – is a code that guarantees the unique identification of a Trade Item anywhere in the world. By the GS1 Standard, it is defined by a numeric sequence of 13 or 14 digits. You can easily switch from a GTIN-13 (13-digit GTIN) to a GTIN-14 (14-digit GTIN) by adding a 0 (zero) as first digit. For further information on the structure of a GTIN code, please refer to GS1 General Specifications.

The GTIN attribute of the GS1 Data Model is defined by a fixed numeric sequence of 14 characters. It's a mandatory attribute of the Data Set and, together with the GNL Information Provider and the Target Market, it constitutes the triad of key information that enables GS1 GDSN processes.

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **Additional Identification Value** | **additionalTradeItemIdentificationValue** | Additional Identification Value used for a cross reference to the GTIN in a one-to-one relation |
| | **additionalTradeItemIdentificationType** | Indicator identifying the type and format of the Additional Trade Item Identification Value |

The Additional Identification Value allows the user to enter in the Data Model an identification value in addition to the standard GTIN. It is defined as optional field of the GDSN Data Set and it can be used according to the user's needs. The "Standard GS1 per l'identificazione e l'allineamento anagrafico in Sanità" Work Group approved the use of this value when entering the Repertory Number relative to the medical device.

Considering the importance that the connection between Medical Device Information data base and GDSN Data Set has in order to avoid the duplication of information and to obtain a complete data base, this attribute must be entered for all the medical devices that are assigned with a Repertory Number. The attribute counts two different information:

- AdditionalTradeItemIdentificationValue identifies the additional identification Value. It is an optional information that can be applied to all package levels; the information field has a variable length with a maximum of 35 alphanumeric characters.
- AdditionalTradeItemidentificationType identifies the type and the format of the value entered before. Therefore, this attribute depends on the additionalTradeItemidentificationValue and its value can be chosen in the CodeList called Additional Trade Item Identification. In support of the need to enter the Repertory Number of the medical devices, as additional identification value, the corresponding type will be selected among the available CodeList choices.

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **Replaced Item GTIN** | **replacedTradeItemIdentification** | GTIN of the trade item being permanently replaced by this trade item |

The Replaced Item GTIN attribute requires to enter in the information field the GTIN of the Trade Item identifier that is being permanently replaced by the one described in the Data Model GS1. The text field is defined by a numerical structure of 14-character fixed length and it is an optional attribute of the Data Set.

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **GLN Provider Information** | **informationProviderOfTradeItem** | GLN that uniquely identifies the information owner/provider |

The Global Location Number – GNL is a code that guarantees the unique identification anywhere in the world of operative units (physical, functional or legal entities, a factory, a warehouse, a distribution center but also a yard or a business function within the same establishment). In GS1 Standard, the GNL is defined by a numerical sequence of 13 digits. For further information on the structure of a GNL code, please refer to GS1 General Specifications. The GLN attribute of the GS1 Data Model is defined by a fixed numeric sequence of 13 digits. It is a mandatory attribute of the Data Set and, together with GTIN attributes and Target Market, it constitutes the triad of key information that enables GS1 GDSN processes.

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **Target Market** | **targetMarketCountryCode** | The target market code indicates the country in which the information provider will make the GTIN available to buyers. This indicator does not in any way govern where the buyer may re-sell the GTIN to consumers |

The Reference Target Market indicates the geographic position where the Data Model entered by the user is valid. As for GLN, this attribute can be applied to all the package hierarchy to be described and it remains constant for all the package levels the Data Model was entered for. The attribute has a 3-digit (numerical) value chosen among the Codelist called "Country Code", obtained from table 3166-1. It is a mandatory attribute of the Data Set and, together with GTIN attributes and Target Market, it constitutes the triad of key information that enables GS1 GDSN processes.


### 3.2.2 "Core" Functional Category: HIERARCHY

The GDSN Data Model includes the description of package levels children of the trade item in question. The attributes included in this category define the content of the described trade item. The following 4 attributes describe the entire content of the trade item they refer to. The following attributes are mandatory and they can be applied to all the hierarchical levels but the base unit (which by definition is the lowest hierarchical level, intended or labeled for individual use).

Let's assume we need to fill out the Data Model for two packaging units, in this case two cardboard boxes arranged as follows:

1. An homogeneous packaging containing 10 packages of identical syringes (all identified by the same GTINX)
2. An inhomogeneous packaging containing packages of syringes with 3 different needle lengths: 3 identified by GTIN 1, 3 identified with GTIN 2 and 2 identified with GTIN 3.

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **Total Quantity of Next Lower Level Trade Item** | **totalQuantityOfNextlowerLevelTradeItem** | Indicates the total number of GTINs contained in a complex trade item. It is derived by summing the Quantity of Next Lower Trade Items of each child GTIN contained in the trade item. |

The Total Quantity of Next Lower Level Trade Item Attribute identifies the overall number of items contained in the described trade item. The attribute is a numeric data field with variable length for a maximum of 6 digits.

In reference to the configuration of the packaging defined at Paragraph 1, the overall quantity of trade items in the lower level is equal to 10, whereas for the configuration defined in Paragraph 2, the overall quantity of trade items in the lower level is equal to 8.

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **Quantity of Children** | **quantityOfChildren** | Indicates the number of unique next lower level trade items contained in a complex trade item. A complex trade item can contain at least two different GTINs. |

The Quantity of Children Attribute indicates the number of different GTIN contained in the described trade item. The attribute is a numeric data field with variable length for a maximum of 10 digits.

In reference to the configuration of the packaging defined at Paragraph 1, the overall quantity of trade items in the lower level is equal to 1, whereas for the configuration defined in Paragraph 2, the overall quantity of trade items in the lower level is equal to 3.

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **Quantity of Next Lower Level Trade Item** | **QuantityOfNextLowerLevelTradeItem** | The quantity of Lower Level Trade Items contained in this trade item |

The Quantity of Next Lower Level Trade Item Attribute indicates the number of different trade items for each GTIN contained in the described trade item. The attribute is a numeric data field with variable length for a maximum of 6 digits.

Compared to the previous two attributes belonging to the same functional category, this and the following attributes can be repeated within the same Data Model.

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **GTIN of next lower level trade item** | **tradeItemIdentificationOfNextLowerLevelTradeItem** | The GTIN of the next lower level trade item that the parent trade item contains |

The Lower Level Trade Item Type attribute defines the Trade Item GTIN contained in the described Trade Item. The attribute is a numeric data field with a fixed length of 14 digits.

Having to indicate all the GTIN contained in a trade item, this and the following attribute can be repeated within the same Data Model.

The two attributes are therefore connected and they define the contained GTIN and the number of trade items contained in the same GTIN.

In reference to the packaging configurations previously indicated:

1. Quantity of Next Lower Level Trade Item 10
   GTIN of next lower level trade item GTINX

2. Quantity of Next Lower Level Trade Item 3
   GTIN of next lower level trade item GTIN1
   Quantity of Next Lower Level Trade Item 3
   GTIN of next lower level trade item GTIN2
   Quantity of Next Lower Level Trade Item 2
   GTIN of next lower level trade item GTIN3

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **Parent GTIN** | **parentGTIN** | The GTIN of the next lower level trade item that the parent trade item contains |

The GTIN attribute of the Parent Trade Item in relation to the Trade Item is currently being developed.

### 3.2.3 "Core" Functional Category: DESCRIPTION

The described attributes characterize the quantity of the described trade item.

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **Brand Name** | **brandName** | The name used by the brand owner to uniquely identify a line of trade items or services. Recognized by costumers |

The Brand attribute indicates the recognizable name used by the brand owner to identify the trade item. The brand is recognizable by the user. The attribute is mandatory and it can be applied to all the different hierarchical levels of the package. It cannot be repeated within the same Data Model.

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The structure of the information field is alphanumeric at variable length for a maximum of 35 characters.

| Attribute Name | XML Name<br>(GS1 GDD Definition) | Definition |
| --- | --- | --- |
| **Functional Name** | **functionalName** | Describes the use of the trade item by the consumer. It should help clarify the product classification associated with the GTIN. |
| **Language** | **functionalNameLanguage** | The Code of the language used to complete the field. |

The Functional Name Attribute requires to specify the active principle or the main characteristic of the device. The question is "What does the product do?". The "Standard GS1 for Healthcare data identification and alignment" Work Group highlighted the opportunity to use the GMDN nomenclature to complete this information field. It is a mandatory attribute of the Data Model that can be applied to all the hierarchical package levels. The Brand Attribute is defined as an alphanumerical attribute with a maximum of 35 characters.

Associated to this field and depending from it, we must introduce a further attribute: the Language - which indicates the code of the language used to complete the "Functional Name" field. This attribute is chosen from a Codelist denominated "Language Code", obtained from the ISO 639-1988 chart.

| Attribute Name | XML Name<br>(GS1 GDD Definition) | Definition |
| --- | --- | --- |
| **Description** | **additionalTradeItemDescription** | Additional descriptive space necessary to communicate the definition of the product. |
| **Language** | **additionalTradeItemDescriptionLanguage** | The Code of the language used to complete the field. |

The Description Attribute allows to enter the textual description of the Medical Device. It is an optional attribute of the Data Model and it is defined as an alphanumerical attribute with a maximum of 350 characters. Associated to this field and depending from it, we must introduce a further attribute: the Language - which indicated the code of the language used to complete the "Functional Name" field. This attribute is chosen from a Codelist denominated "Language Code", obtained from the ISO 639-1988 chart.

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **Brand Owner GLN** | **brandOwner** | Unique identifier for the brand owner. May or may not be the same entity as the information provider, which actually enters and maintains data in data pools. Preference is GLN. |

The Global Location Number – GNL is a code that guarantees the unique and unequivocal identification anywhere in the world of operative units (physical, functional or legal entities, a factory, a warehouse, a distribution center but also a yard or a business function within the same establishment). In GS1 Standard, it is defined by a numerical sequence of 13 digits. For further information on the structure of a GNL code, please refer to GS1 General Specifications. The GLN attribute of the GS1 Data Model is defined by a fixed numeric sequence of 13 digits.

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **Name of Brand Owner** | **nameOfBrandOwner** | Name of the party who owns the brand of the item. |

The Name of Brand Owner Attribute indicates the name of the brand owner. The Name of the Brand Owner is recognizable by the user. The attribute is optional and it can be applied to all the different hierarchical levels of the package. It cannot be repeated within the same Data Model. The structure of the information field is alphanumeric at variable length for a maximum of 35 characters.

The GNL Brand Owner and Name of Brand Owner attributes are optional but they are connected to each other. If the user enters one of the two, the other one is automatically enabled and it becomes therefore mandatory.

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **Manufacturer GLN** | **manufacturer** | The Entity issuing the GTIN associated to the trade item, usually the manufacturer of the item. Only one entity per GTIN. Preference is GLN. |

The GNL (Global Location Number) is a code that guarantees the unique and unequivocal identification anywhere in the world of operative units (physical, functional or legal entities, a factory, a warehouse, a distribution center but also a yard or a business function within the same establishment). In GS1 Standard, it is defined by a numerical sequence of 13 digits. For further information on the structure of a GNL code, please refer to GS1 General Specifications. The GLN attribute of the GS1 Data Model is defined by a fixed numeric sequence of 13 digits.

| Attribute Name | XML Name<br>(GS1 GDD Definition) | Definition |
|---|---|---|
| **Name of Manufacturer** | **nameOfManufacturer** | The Entity issuing the GTIN associated to the trade item, usually the manufacturer of the item. Only one entity per GTIN. |

The Name of Manufacturer Attribute indicates the name of the entity producing the trade item. The attribute is optional and it can be applied to all the different hierarchical levels of the package. It cannot be repeated within the same Data Model. The structure of the information field is alphanumeric at variable length for a maximum of 35 characters. The GLN Manufacturer and Name of Manufacturer attributes are optional but they are connected to each other. If the user enters one of the two, the other one is automatically enabled and it becomes therefore mandatory.

### 3.2.4 "Core" Functional Category: CLASSIFICATION

| Attribute Name | XML Name<br>(GS1 GDD Definition) | Definition |
|---|---|---|
| **Brick Code for GPC Classification** | **classificationCategoryCode** | GPC classification category Classification Code ("brick") A 8-digit unique and permanent code Mandatory information for synchronization process. |

The Brick Code for GPC Classification Attribute is mandatory and it requires to enter the GPC code for product classification developed by GS1. The GS1 GPC Classification system divides products into several categories in accordance to their reference market. Through GPC, each product is associated to a unique code that identifies the product market. Since the GPC Healthcare System for pharmaceutical products and medical devices hasn't been developed yet, this field cannot yet be entered for all trade items.

Therefore, there are two possibilities for the user:

1. 1) to use a dummy code: 99999999
2. 2) to use the 10005845 code for pharmaceutical products and 10005844 code for medical devices.

| Attribute Name | XML Name<br>(GS1 GDD Definition) | Definition |
|---|---|---|
| **Additional Classification Agency Name** | **additionalClassificationAgencyName** | The name of the agency that maintains the additional classification system. |

The Attribute indicates the code of the Agency maintaining the non-GPC classification for medical devices. The Attribute can be entered only for the medical device base unit and it is optional. The value to be assigned the field with is chosen from a Codelist called "Additional Classification Agency Name" and for the Italian solution here described, the "Standard GS1 for Healthcare data identification and alignment" Work Group decided to enter the CND code (National Classification of

Medical Devices) as additional classification. The Codelist to complete this field already contains the value defined by CND.

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **Additional Classification Category Code** | **additionalClassificationCategoryCode** | Category code based on an alternate product classification system chosen in addition to the GPC one. |

The Additional Classification Category Code Attribute depends on the previous one and it indicates the value of the chosen additional classification. If the Additional Classification Agency Name Attribute is enabled, this attribute must be entered as well, and it applies only to the base unit and it is defined by a alphanumerical information field with variable length for a maximum of 15 characters.

The Additional Classification Agency Name and Additional Classification Category Code attributes can both be repeated within the Data Model; it is therefore allowed to repeat them to enter further additional classifications, e.g. GMDN, EDMA etc.

### 3.2.5 "Core" Functional Category: MEASUREREMENTS

Attributes defined for the measurement functional category are used to describe the trade item from a dimensional point of view. All measurement attributes are associated to and dependant from a second attribute: the unit of measure defining the value entered in the previous attribute. The attribute that defines the unit of measure is chosen from a Codelist.

All trade items are described by measurement attribute defined by the Data Model. For further information on the methods of trade item measure calculation, please refer to "GS1 Package Measurement Rules".

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **Height** | **height** | The height of a trade item. The vertical dimension from the base to the top, packaging included. With pallets, the measurement include the height of the pallet as well. |
| **Unit of Measurement** | **heightUOM** | The chosen code defines the value of the previous attribute. |

The attribute defines the height of the trade item and it can be applied to all the hierarchical levels of the package. It is a mandatory attribute for the GS1 GDSN Healthcare Data Model with a numerical structure with variable length for a maximum of 15 digits.

The Unit of Measurement Attribute depends on the value entered for the Height Attribute and its value is defined by a Codelist called "Linear Unit of Measure".

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **Width** | **width** | Width is the measurement from left to right. |
| **Unit of Measurement** | **widthUOM** | The chosen code defines the value of the previous attribute. |

The attribute defines the width of the trade item and it can be applied to all the hierarchical levels of the package. It is a mandatory attribute for the GS1 GDSN Healthcare Data Model with a numerical structure with variable length for a maximum of 15 digits. The Unit of Measurement Attribute depends on the value entered for the Width Attribute and its value is defined by a Codelist called "Linear Unit of Measure".

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **Depth** | **depth** | Depth is the measurement from front to back. |
| **Unit of Measurement** | **depthUOM** | The chosen code defines the value of the previous attribute. |

The attribute defines the depth of the trade item and it can be applied to all the hierarchical levels of the package. It is a mandatory attribute for the GS1 GDSN Healthcare Data Model with a numerical structure with variable length for a maximum of 15 digits. The Unit of Measurement Attribute depends on the value entered for the Depth Attribute and its value is defined by a Codelist called "Linear Unit of Measure".

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **Net Content** | **netContent** | The amount of the trade item contained by a package, usually as claimed on the label. Note: To specify only for Consumer Unit |
| **Unit of Measurement** | **netContentUOM** | The chosen code defines the value of the previous attribute. |

The Net Content attribute of the trade item can be applied only to the trade item, the lowest in hierarchy. It requires to enter the net content of the item. For example:

- If the trade item is a bottle containing 500 ml of a saline solution, the net content of the device is 500 ml;
- If the trade item is a package of 50 syringes, the net content is 50 pieces.

It is a mandatory attribute for the GS1 GDSN Healthcare Data Model with a numerical structure with variable length for a maximum of 15 digits.

The Unit of Measurement Attribute depends on the value entered for the Depth Attribute and its value is defined by a Codelist called "Size Unit of Measure".

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **Gross Weight** | **grossWeight** | Used to identify the gross weight of the trade item. The trade item gross weight, inclusive of its packaging. |
| **Unit of Measurement** | **grossWeightUOM** | The chosen code defines the value of the previous attribute. |

The attribute defines the gross weight of the trade item and it can be applied to all the hierarchical levels of the package. It is a optional attribute for the GS1 GDSN Healthcare Data Model with a numerical structure with variable length for a maximum of 15 digits. The Unit of Measurement Attribute depends on the value entered for the Gross Weight Attribute and its value is defined by a Codelist called "Weight Unit of Measure".

### 3.2.6 "Core" Functional Category: INDICATORS

In the Indicator Functional Category we find all the attributes defining the catalogue trade. The Attributes defined in this category are all mandatory and they have a Boolean structure that the user must define as Yes or No.

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **Base Unit** | **isTradeItemABaseUnit** | Indicator identifying the item as the base unit level of the trade item |

The attribute requests if the trade unit corresponds to the lowest base unit level for the medical device. It can be entered for all the hierarchical levels of a package and it cannot be repeated within the same Data Model.

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **Consumer Unit** | **isTradeItemAConsumerUnit** | Indicator identifying if the current hierarchy level of the trade item is intended to ultimate consumption. For retailers, this item can be scanned in the point of sale |

The attributes requests if the trade unit corresponds to the consumer unit. It can be entered for all the hierarchical levels of a package and it cannot be repeated within the same Data Model.

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **Despatch Unit** | **isTradeItemADespatchUnit** | Indicator identifying the item as a despatch (shipping) unit, for the information provider. |

The attributes requests if the trade unit corresponds to the dispatch unit ready for shipment. It can be entered for all the hierarchical levels of a package and it cannot be repeated within the same Data Model.

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **Invoice Unit** | **isTradeItemAnInvoiceUnit** | Indicator identifying the item as an invoicing unit, per the information provider. |

The attributes requests if the trade unit corresponds to the invoice unit. It can be entered for all the hierarchical levels of a package and it cannot be repeated within the same Data Model.

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **Orderable Unit** | **isTradeItemAnOrderableUnit** | Indicator identifying the item as an orderable unit to customers, per the information provider. |

The attributes requests if the trade unit corresponds to the orderable unit. It can be entered for all the hierarchical levels of a package and it cannot be repeated within the same Data Model.

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **Trade Item Variable Unit** | **isTradeItemAVariableUnit** | Indicates trade item is not a fixed weight. |

The attributes requests if the trade unit corresponds to the variable unit (for quantity or weight). It can be entered for all the hierarchical levels of a package and it cannot be repeated within the same Data Model.

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **Batch Number** | **hasBatchNumber** | It indicates if a batch number is assigned to a trade item. A batch or lot number is a manufacturer assigned code used to identify a trade item's production batch or lot. Differs from Serial Number which is always a manufacturer assigned code to identify a unique trade item. |

In accordance with its definition, the serial number - which is usually associated to the production of a Medical device - univocally identifies a product/object and it cannot be assimilated to a batch number which has been assigned to a group of items. Therefore, the attribute must be filled in with a negative answer if the described object has a Serial Number but no Batch number.

The attribute requests if the trade unit is assigned with a production/packing batch. It can be entered for all the hierarchical levels of a package and it cannot be repeated within the same Data Model.

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **Non-Sold Trade Item returnable** | **isNonSoldTradeItemReturnable** | Indicates the non-sold/non-used trade item can be returned |

The attributes requests if the trade unit corresponds to the non-sold returnable unit. It can be entered only for the consumer unit, the lowest in hierarchy, and it cannot be repeated within the same Data Model.

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **Recyclable Trade Item** | **isTradeItemMarkedAsRecyclable** | Trade item has a recyclable indication marked on it. |

The attributes requests if the labeled trade unit is recyclable. It can be entered only for the consumer unit, the lowest in hierarchy and it cannot be repeated within the same Data Model.


### 3.2.7 "Core" Functional Category: DATES

The Date Category includes three mandatory attributes that are meant to enable the validity of the Data Model entered in the trade item catalogue. They apply to all hierarchical levels and they cannot be repeated within the same Data Model. The structured defined for all attributes is the data and time ISO standard: YYYY-MM-DDTHH:MM:SS - as saying they will be assigned with 4 digits for the year, 2 for the month, 2 for the day, 2 for the hour, 2 for the minutes and 2 for the

seconds. If it is not necessary or possible to enter one or more of the above-mentioned information about date and time, the relative space shall be filled in with 0 (zeros).

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **Effective Start Date** | **effectiveDate** | The effective start date of the catalogue price agreed to by trading partners. This date can be intended as offer start date of the trade item or it can indicates a change of information related to an existing trade item. This date indicates when a change becomes effective. |

The Trade Item Effective Start Date Attribute requires to indicate the effective date and time from which the loaded Data Model becomes valid and therefore usable.

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **Start Availability Date Time** | **startAvailabilityDateTime** | The date from which the trade item becomes available from the supplier. It includes seasonal or temporary trade items. |

The Trade Item Start Availability Date Attribute requires to indicate the effective date and time from which the loaded Data Model becomes available to buyers.

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **Publication Date** | **publicationDate** | The date on which all static data associated with the trade item becomes available for viewing and synchronization. |

The Trade Item Publication Date Attribute requires to indicate the effective date and time at which the Data Model is published.

### 3.2.8 "Core" Functional Category: PACKAGING

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **Returnable Packaging** | **isPackagingMarkedReturnable** | Trade item has returnable packaging (return expected). |

The Returnable Packaging Attribute requests to indicate if the labeled packaging can be returned and, therefore, reused. It is mandatory and it is applied to all hierarchical package levels with no permission to repeat within the same Data Model. The structure of the Returnable Packaging Attribute is Boolean and, therefore, it requires a Yes or No answer.

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **BarCode Type** | **barCodeType** | The symbology of the barcode or codes that are visible on the trade item. |

The Barcode Type requests to indicate the type of visible barcode used for labeling the trade item. It is an optional attribute and it can be applied to all the hierarchical package levels and it can be repeated within the same Data Model if the same trade item is provided with several types of barcode. The value assigned to the attribute can be chosen in the Codelist called Barcode Type.

### 3.2.9 "Core" Functional Category: PRESERVATION AND MAINTENANCE

The attributes belonging to the Preservation and Maintenance Functional Category are optional and they are used for a description of the physical preservation and maintenance of the trade item.

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **Minimum Trade Item Lifespan from Time of Arrival** | **minimumTradeItemLifespanFromTimeOfArrival** | The period of days guaranteed by the manufacturer before the expiration date of the trade item, based on arrival at a mutually agreed to point in the buyer's distribution system. |

The Minimum Trade Item Lifespan from Time of Arrival Attribute requests to indicate (in days) the Life span of the device from the time of delivery. As saying, it indicates the number of days, guaranteed by the manufacturer, before the expiration date of the trade item, based on the arrival at the point of distribution. This attribute is compatible only to the trade item and it cannot be repeated within the same Data Model. The structure of the information field is defined by an alphanumerical field with variable length up to a maximum of 4 characters.

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **Minimum Trade Item Lifespan from Time of Arrival** | **minimumTradeItemLifespanFromTimeOfProduction** | The period of days guaranteed by the manufacturer before the expiration date of the trade item, based upon the production date. |

The Minimum Trade Item Lifespan from Time of Arrival Attribute requires to indicate (in days) the Life span of the device from the date of production. As saying, it indicates the number of days, guaranteed by the manufacturer, before the expiration date of the trade item, based on the date of production. This attribute is compatible only to the trade item and it cannot be repeated within the same Data Model. The structure of the information field is defined by an alphanumerical field with variable length up to a maximum of 4 characters.

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **Storage Handling Temperature Maximum** | **storageHandlingTemperatureMaximum** | The maximum temperature at which the trade item can the stored. |
| **Unit of Measurement** | **storageHandlingTemperatureMaximumUOM** | The chosen code defines the value of the previous attribute. |

The Storage Handling Temperature Maximum Attribute is an attribute that can be applied to all the hierarchical level of the package, obviously maintaining the same value in the describe hierarchy. It cannot be repeated within the same Data Model. It is a optional attribute for the GS1 GDSN Healthcare Data Model with a numerical structure with variable length for a maximum of 15 digits.

To this information it is associated another dependant attribute: unit of measure defining the value entered in the previous attribute. The attribute that defines the unit of measure is chosen from a Codelist denominated Temperature Unit of Measure.

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **Storage Handling Temperature Minimum** | **storageHandlingTemperatureMinimum** | The minimum temperature at which the trade item can the stored. |
| **Unit of Measurement** | **storageHandlingTemperatureMinimumUOM** | The chosen code defines the value of the previous attribute. |

The Storage Handling Temperature Minimum Attribute is an attribute that can be applied to all the hierarchical level of the package, obviously maintaining the same value in the describe hierarchy. It cannot be repeated within the same Data Model. It is a optional attribute for the GS1 GDSN Healthcare Data Model with a numerical structure with variable length for a maximum of 15 digits. To this information it is associated another dependant attribute: unit of measure defining the value entered in the previous attribute. The attribute that defines the unit of measure is chosen from a Codelist denominated Temperature Unit of Measure.

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **Handling Humidity Maximum** | **storageHandlingHumidityMaximum** | The maximum humidity at which the trade item can the handled. |

| Unit of Measurement | storageHandlingHumidityMaximumUOM | The chosen code defines the value of the previous attribute. |
|---|---|---|

The Attribute defines the percentage of Maximum Humidity of Storage Handling. It is an attribute that can be applied to all the hierarchical level of the package, obviously maintaining the same value in the describe hierarchy. It cannot be repeated within the same Data Model. It is a optional attribute for the GS1 GDSN Healthcare Data Model with a numerical structure with variable length for a maximum of 3 digits. To this information it is associated another dependant attribute: unit of measure defining the value entered in the previous attribute. The attribute that defines the unit of measure is chosen from a Codelist denominated Size Unit of Measure where to choose the value: Percent.

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **Handling Humidity Minimum** | **storageHandlingHumidityMinimum** | The minimum humidity at which the trade item can the handled. |
| **Unit of Measurement** | **storageHandlingHumidityMaximumUOM** | The chosen code defines the value of the previous attribute. |

The attribute defines the percentage of minimum humidity of storage handling for the trade item. It is an attribute that can be applied to all the hierarchical level of the package, obviously maintaining the same value in the describe hierarchy. It cannot be repeated within the same Data Model. It is a optional attribute for the GS1 GDSN Healthcare Data Model with a numerical structure with variable length for a maximum of 3 digits. To this information it is associated another dependant attribute: unit of measure defining the value entered in the previous attribute. The attribute that defines the unit of measure is chosen from a Codelist denominated Size Unit of Measure where to choose the value: Percent.

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **Class of Dangerous Goods** | **classOfDangerousGoods** | Dangerous goods classification of the trade item. |

The Class of Dangerous Goods Attribute is optional and it was chosen by the "Standard GS1 for Healthcare data identification and alignment" Work Group to indicate if the described trade item is radioactive or not. The attribute value is defined within a Codelist called Class of Dangerous Goods in which it is possible to choose further values related to the Danger Level of the trade item. The code indicating radioactivity of a trade item in number 7. The Attribute can be associated to all the hierarchical levels of a package and it can be repeated within the same Data Model.

### 3.2.10  "Extension" Functional Category: HEALTHCARE

The attributes described below belong to the Healthcare Extension of GS1 GDSN Data Model Core. They have been specifically developed to support the needs of description specifically deriving from this product sector. All the attributed defined for the Healthcare sector are optional and they can be entered for all the hierarchical levels but pallets. In particular, they refer to the

base unit and they cannot be repeated within the same Data Model. The values given to the attributes are all defined by specific Codelists.

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **Trade Item Contains Human Blood or derivate** | **doesTradeItemContainHumanBloodDerivative** | Identifies if the trade item contains human blood, components or derivate. |

The attribute requires to indicate if the trade item contains blood, blood components or derivates. The value assigned to the attribute is defined by a Codelist called Non-Binary Logic.

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **Contain Latex** | **doesTradeItemContainLatex** | Identifies if the trade item is produced or contained latex. This last statement generally refers to a stable dispersion (emulsion) of polymer micro-particles in a aqueous medium. |

The attribute requires to indicate if the trade item is produced or contains latex. The value assigned to the attribute is defined by a Codelist called Non-Binary Logic.

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **Implantable** | **isTradeItemimplantable** | Identifies if the trade item is implantable. |

The attribute requires to indicate if the device is implantable. A device is defined as implantable if it can be fully or partially inserted into the human body: e.g., heart valves and orthopedic implants are considered implantable devices. The value assigned to the attribute is defined by a Codelist called Non-Binary Logic.

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **Brand or Generic** | **isTradeItemConsideredGeneric** | Identifies if the trade item can be used as generic substitute of a brand trade item. A FALSE value identifies a trade item that cannot be considered a generic substitute. |

The attribute requires to indicate if the device is to be considered a brand or a generic substitute of a brand trade item. The value assigned to the attribute is defined by a Codelist called Non-Binary Logic.

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **Reusable** | **manufacturerDeclaredReusabilityType** | Defines if the trade item is for single use only or if it can be reused (if so, how). |

The attribute requires to indicate if the trade item is for single use only or reusable. The declaration is guaranteed by the manufacturer who specifies if the product is reusable or not, if it has a limited reuse or if it can be reused only for certain patients. The value assigned to the attribute is defined by a Codelist called Healthcare Trade Item Reusability TypeCode List.

In combination to this attribute, 3 other optional attributes were defined to more specifically describe the characteristics of product reusability:

- **Maximum Reusable Cycles**: the attribute defines the maximum times a device can be reused.

- **Maximum Reusable Days:** the attribute defines the maximum time a device can be reused, in terms of days.

- **Reuse Instruction**: the textual attribute allows the manufacturer to specify the instruction of device reusability.

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **Initial Sterilisation** | **initialManufacturerSterilisation** | Type(s) of sterilisation(s) carried out by the manufacturer |

The attribute requires to identify which type(s) of sterilisation was (were) carried out by the manufacturer on the described item.

"Sterilisation" refers to any process that kills or effectively eliminates the transmissible agents (such as fungi, bacteria, viruses, prions and spore forms, ...) from surfaces, equipments, food, drugs and medical devices, etc.

Certain methods of sterilisation can be carried out with the use of heat, radiations and ethylene.

| Attribute Name | XML Name (GS1 GDD Definition) | Definition |
|---|---|---|
| **Initial Sterilisation Prior to Use** | **initialSterilisationPriorToUse** | Type(s) of sterilisation(s) the healthcare operator must carry out before the first of the trade item |

The attribute requires to indicate which type(s) of stelizations the healthcare operator must carry out on the described item before its first use.

"Sterilisation" refers to any process that kills or effectively eliminates the transmissible agents (such as fungi, bacteria, viruses, prions and spore forms, ...) from surfaces, equipments, food, drugs and medical devices, etc. Certain methods of sterilisation can be carried out with the use of heat, radiations and ethylene.

The attribute is optional and its assigned value is defined by a Codelist called HC Sterilisation Type.

| Attribute Name | XML Name<br>(GS1 GDD Definition) | Definition |
|---|---|---|
| **Acceptable Resterilisations** | **manufacturerSpecifiedAcceptableResterilisation** | Type(s) of acceptable resterilisation(s) the healthcare operator can conduct (if reusable unit). |

The attribute requires to indicate which type(s) of allowed sterilisations the healthcare operator can conduct in case the described trade item is defined as reusable.

"Sterilisation" refers to any process that kills or effectively eliminates the transmissible agents (such as fungi, bacteria, viruses, prions and spore forms, ...) from surfaces, equipments, food, drugs and medical devices, etc. Certain methods of sterilisation can be carried out with the use of heat, radiations and ethylene..

The attribute is optional and its assigned value is defined by a Codelist called HC Sterilisation Type.

| Attribute Name | XML Name<br>(GS1 GDD Definition) | Definition |
|---|---|---|
| **Unit required to remain sterile** | **isTradeItemRequiredToRemainSterile** | Identifies if a sterile trade item must remain sterile from the moment of sterilisation until administering. |

The attribute requires to indicate if the sterile trade item must remain sterile from the moment of sterilisation until administering. The attribute is optional and its assigned value is defined by a Codelist called Non-Binary Logic.

| Attribute Name | XML Name<br>(GS1 GDD Definition) | Definition |
|---|---|---|
| **Concern/Safety Indicator** | **contentOfConcern** | Safety Concern Indicator and, therefore, the concern level related to the trade item. |

The Concern/Safety Indicator attribute related to the Trade Item is currently being developed.

### *Annex A:* Data Model for Healthcare Trade Item Master Data, rev. ITA_1.0.1_072012

| Class of attribute | Attribute Name | Name XML (GS1 GDD Definition) | Definition | State M: mandatory O: optional D: dependant Pending: under development |
|---|---|---|---|---|
| **Identification** | Hierarchy Level (of package) | tradeItemUnitDescriptor | Identifies the hierarchical configuration of the trade item (e.g., pallet, case, inner pack, mixed module, display shipper, base unit, prepack, setpack, multipack, etc.) | M |
| | Item GTIN | globalTradeItemNumber | The Global Trade Item Number (GTIN) is used for the unique identification of trade items worldwide. 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, ordered, or invoiced at any point in any supply chain. | M |
| | Additional Identification Value | additionalTradeItemIdentificationValue | The information provider's internal number for the trade item, used to cross-reference to the GTIN in a one-to-one relationship | O |
| | | additionalTradeItemIdentificationType | Indicator identifying the type and format of the Additional Trade Item Identification Value | D |
| | Replaced Item GTIN | replacedTradeItemIdentification | GTIN of the trade item being permanently replaced by this trade item | O |
| | GLN Information Provider | informationProviderOfTradeItem | GLN that uniquely identifies the data owner/information provider (e.g. manufacturer, supplier, broker, distributor, etc.) | M |
| | Target Market | targetMarketCountryCode | The target market code indicates the country in which the information provider will make the GTIN available to buyers. This indicator does not in any way limit or govern where the buyer may re-sell the GTIN to consumers | M |
| **Hierarchy** | Total Quantity of Next Lower Level Trade Item | totalQuantityOfNextLowerLevelTradeItem | Indicates the total number of GTINs contained in a complex trade item. It is derived by summing the Quantity of Next Lower Trade Item of each child GTIN contained in the trade item. | M |
| | Quantity of Children | quantityOfChildren | Indicates the number of unique next lower level trade items contained in a complex trade item. A complex trade item can contain at least two different GTINs. | M |
| | Quantity of Next Lower Level Trade Item | quantityOfNextLowerLevelTradeItem | The quantity of Trade Item of Lower Level contained in this trade item (e.g. number of CU in CA) | M |

| | | | | |
|---|---|---|---|---|
| | GTIN of next lower level trade item | tradeItemIdentificationOfNextLowerLevelTradeItem | The GTIN of the next lower level trade item that the parent trade item contains | M |
| | Parent GTIN | parentGTIN | The GTIN of the next lower level trade item that the parent trade item contains | Pending |
| **Description** | Brand Name | brandName | The name used by the brand owner to uniquely identify a line of trade items or services. Recognized by costumers | M |
| | Functional Name | functionalName | Describes use of the trade item by the consumer. It should help clarify the product classification associated with the GTIN. | M |
| | Description | additionalTradeItemDescription | Additional descriptive information necessary to communicate the definition of the product. Multiple Variants can be defined for each GTIN. | O |
| | Brand Owner GLN | brandOwner | Unique identifier for the brand owner. May or may not be the same entity as the information provider, which actually enters and maintains data in data pools. Preference is GLN. | O |
| | Name of Brand Owner | nameOfBrandOwner | Name of the party who owns the brand of the item. | O |
| | Manufacturer GLN | Manufacturer | The Entity issuing the GTIN associated to the trade item, usually the manufacturer of the item. Only one entity per GTIN. Preference is GLN. | O |
| | Name of Manufacturer | nameOfManufacturer | The Entity issuing the GTIN associated to the trade item, usually the manufacturer of the item. Only one entity per GTIN. | O |
| **Classification** | Brick Code for GPC Classification | classificationCategoryCode | GPC classification category Classification Code ("brick") A 8-digit unique and permanent code Mandatory information for synchronization process. For Healthcare, the GPC tree has not yet been completely developed. For this, the field cannot be yet filled with the correct GPC value. Therefore, there are two possibilities for the agency: 1) to use a dummy code: 99999999 2) to use the 10005845 code for pharmaceutical products and 10005844 code for medical devices. | M |
| | Additional Classification Agency Name | additionalClassificationAgencyName | The name of the agency that maintains the additional classification system. | O |
| | Additional Classification Category Code | additionalClassificationCategoryCode | Category code based on an alternate product classification system chosen in addition to the EAN*UCC | D |
| **Measures** | Height | height | The height of a trade item. The Vertical dimension from base to the top, packaging included. With pallets, the measurement include the height of the pallet as well. | M |
| | Width | width | Width is the measurement from left to right. | M |

| | Depth | depth | Depth is the measurement from front to back. | M |
|---|---|---|---|---|
| | Net Content | netContent | The amount of the trade item contained by a package, usually as claimed on the label. Note: To specify only for Consumer Unit | M |
| | Gross Weight | grossWeight | Used to identify the gross weight of the trade item. The trade item gross weight, inclusive of its packaging. | O |
| **Indicators** | Base Unit | isTradeItemABaseUnit | Indicator identifying the item as the base unit level of the trade item | M |
| | Consumer Unit | isTradeItemAConsumerUnit | Indicator identifying if the current hierarchy level of the trade item is intended to ultimate consumption. For retailers, this item can be scanned in the point of sale | M |
| | Dispatch Unit | isTradeItemADespatchUnit | Indicator identifying the item as a dispatch (shipping) unit, per the information provider. | M |
| | Invoice Unit | isTradeItemAnInvoiceUnit | Indicator identifying the item as an invoicing unit, per the information provider. | M |
| | Orderable Unit | isTradeItemAnOrderableUnit | Indicator identifying the item as an ordering unit to customers, per the information provider. | M |
| | Trade Item Variable Unit | isTradeItemAVariableUnit | Indicates trade item is not a fixed weight. | M |
| | Batch Number | hasBatchNumber | It indicates if a batch number is assigned to a trade item. A batch or lot number is a manufacturer assigned code used to identify a trade item's production batch or lot. Differs from Serial Number which is always a manufacturer assigned code to identify a unique trade item. | M |
| | Non-Sold Trade Item returnable | isNonSoldTradeItemReturnable | Indicates the non-sold/non-used trade item can be returned | M |
| | Recyclable Trade Item | isTradeItemMarkedAsRecyclable | Trade item has a recyclable indication marked on it. | M |
| **Date** | Effective Start Date | effectiveDate | The effective start date of the catalogue price agreed to by trading partners. This date can be intended as offer start date of the trade item or it can indicates a change of information related to an existing trade item. This date indicates when a change becomes effective. | M |
| | Start Availability Date Time | startAvailabilityDateTime | The date (yyyy-mm-ddThh:mm:ss) from which the trade item becomes available from the supplier. It includes seasonal or temporary trade items. | M |
| | Publication Date | publicationDate | The date on which all static data associated with the trade item becomes available for viewing and synchronization. | M |
| **Packaging** | Returnable Packaging | isPackagingMarkedReturnable | Trade item has returnable packaging (return expected). | M |

| | | | | |
|---|---|---|---|---|
| | BarCode Type | barCodeType | The symbology of the barcode or codes that are visible on the trade item. | O |
| **Preservation and Maintenance** | Minimum Trade Item Lifespan from Time of Arrival | minimumTradeItemLifespanFromTimeOfArrival | The period of days guaranteed by the manufacturer before the expiration date of the trade item, based on arrival at a mutually agreed to point in the buyer's distribution system. | O |
| | Minimum Trade Item Lifespan from Time of Arrival | minimumTradeItemLifespanFromTimeOfProduction | The period of days guaranteed by the manufacturer before the expiration date of the trade item, based upon the production date. | O |
| | Storage Handling Temperature Maximum | storageHandlingTemperatureMaximum | The maximum temperature at which the trade item can the stored. | O |
| | Storage Handling Temperature Minimum | storageHandlingTemperatureMinimum | The minimum temperature at which the trade item can the stored. | O |
| | Handling Humidity Maximum | storageHandlingHumidityMaximum | The maximum humidity at which the trade item can the handled. | O |
| | Handling Humidity Minimum | storageHandlingHumidityMinimum | The minimum humidity at which the trade item can the handled. | O |
| | Class of Dangerous Goods | classOfDangerousGoods | Dangerous goods classification of the trade item. | O |

| | | | | |
|---|---|---|---|---|
| **Healthcare Extension** | Trade Item Contains Human Blood or derivate | doesTradeItemContainHumanBloodDerivative | Identifies if the trade item contains human blood, components or derivate. | O |
| | Contain Latex | doesTradeItemContainHumanLatex | Identifies if the trade item is produced or contained latex. This last statement generally refers to a stable dispersion (emulsion) of polymer micro-particles in a aqueous medium. | O |
| | Trade item Implantable | isTradeItemImplantable | Identifies if the trade item is implantable. | O |
| | Brand or Generic | isTradeitemConsideredGeneric | Identifies if the trade item can be used as generic substitute of a brand trade item. A FALSE value identifies a trade item that cannot be considered a generic substitute. | O |
| | Reusable | manufacturerDeclaredReusabilityType | Defines if the trade item is for single use only or if it can be reused (if so, how). | O |
| | Initial Sterilisation | initialManufacturerSterilisation | Type(s) of sterilisation(s) carried out by the manufacturer | O |
| | Initial Sterilisation Prior to Use | initialSterilisationPriorToUse | Type(s) of sterilisation(s) the healthcare operator must carried out before the first of the trade item | O |

| | Acceptable Resterilisation | manufacturerSpecifiedAcceptableResterilisation | Type(s) of acceptable resterilisation(s) the healthcare operator can conduct (if reusable unit). | O |
| --- | --- | --- | --- | --- |
| | Unit required to remain sterile | isTradeItemRequiredToRemainSterile | Identifies if a sterile trade item must remain sterile from the moment of sterilisation until administering. | O |
| | Concern/Safety Indicator | contentOfconcern | Safety Concern Indicator and, therefore, the concern level related to the trade item. | Pending |