

The Global Language of Business

GS1 Healthcare US

Best Practice Guide for Sharing Vital Attributes in Healthcare

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About GS1 Healthcare

GS1 Healthcare is a global, voluntary healthcare user group developing global standards for the healthcare supply chain and advancing global harmonization. GS1 Healthcare consists of participants from all stakeholders of the healthcare supply chain: manufacturers, wholesalers, and distributors, as well as hospitals and pharmacy retailers. GS1 Healthcare also maintains close contacts with regulatory agencies and trade organizations worldwide. GS1 Healthcare drives the development of GS1 Standards and solutions to meet the needs of the global healthcare industry and promotes the effective utilization and implementation of global standards in the healthcare industry through local support initiatives like GS1 Healthcare US® in the United States.

About GS1 Healthcare US

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The Healthcare Supply Chain Association (HSCA) represents the nation's leading healthcare group purchasing organizations (GPOs), which are critical cost-savings partners to America's hospitals, homes, nursing home pharmacies, clinics, home healthcare providers and surgery centers. GPOs deliver billions in savings annually to healthcare providers, Medicare and Medicaid, and taxpayers. HSCA and its member GPOs are committed to delivering the best products at the best value to healthcare providers.

About the Committee for Healthcare eStandards (CHeS)

CHeS is working committee of HSCA and a leader in the healthcare industry's efforts to improve accuracy, efficiency, and patient safety through the application of electronic data standards in the healthcare supply chain. CHeS works across sectors to accelerate industry-wide deployment of the standards and associated processes throughout the healthcare supply chain.



Document Summary

Document Item	Current Value
Document Title	Best Practice Guide for Sharing Vital Attributes in Healthcare
Date Last Modified	June 2021
Document Description	This document provides best practice guidance for healthcare industry members intending to share data about medical devices or pharmaceutical products.



1 Introduction

This document provides best practice guidance for healthcare industry members intending to share data about medical devices or pharmaceutical products. While these best practices are provided with some specificity to sharing data via the GS1 Global Data Synchronization Network[™] (GDSN[®]), the intention was to outline best practices at the attribute level, irrespective of the sharing method. Healthcare stakeholders will likely continue to use a variety of sources for providing and obtaining information about the products they sell, buy, and use in the administration of patient care. Whether data is shared one to one via spreadsheets or text files or downloaded from the U.S. FDA Global Unique Device Identification Database (GUDID) or shared in a one to many tool like GDSN, the data found in these sources should be complete and consistent across all data sources and industry trading partners. GS1 worked closely with the Healthcare Supply Chain Association's (HSCA) Committee for Healthcare eStandards and cross-industry members of the GS1 Healthcare US Industry Initiative Data Quality & Value of Trusted Data workgroup to develop this guidance and best practices document to support healthcare organizations in sharing vital attribute data that meets the definition of "trusted data" as defined in Figure 1.

In order to achieve interoperability in healthcare, the workgroup believes that the structure and content of data must be able to be readily synchronized, which requires all trading partners to be aligned on the format, structure, and content at the attribute level. These best practices are intended to enable more seamless data synchronization between healthcare trading partners in order to achieve that interoperability.

Figure 1-1 Elements of Trusted Data

Accurate

- Data provided is aligned with how it is viewed or used by trading partners
- Data provided matches the label

Complete

 Data needed for different business processes or decision making means a variety of data elements are needed by trading partners

Timely

 Real time as much as possible; a lot of business takes place in 30 days

Consistent

• Multiple data sources used by trading partners need to have consistent core information

Synchronized

Collaboration across trading partners is essential to achieve data needs



Important: As with all GS1 Standards and solutions, the *Best Practice Guide for Sharing Vital Attributes in Healthcare* is voluntary, not mandatory. It should be noted that use of the words "must" and "require" throughout this document relate exclusively to technical recommendations for the proper application of the standards to support the integrity of your implementation.

GS1 US is not offering legal services or advice on the Company's regulatory compliance requirements. Each company is individually responsible for meeting all statutory and/or regulatory requirements for their company and their products. Consult with your company's legal



counsel or compliance team for more specific information about statutory and regulatory requirements.

1.1 Document Purpose

The purpose of this document is to supplement the documents listed below by providing guidance to increase accuracy, completeness, and consistency of vital attributes needed to support basic healthcare processes. The belief is that, if all healthcare stakeholders, both data sources and data recipients, will support these recommended best practices at the attribute level, trading partners' ability to trust and seamlessly synchronize shared data will improve. Aligning at this level from end to end of the supply chain will promote data accuracy, efficiency, and interoperability.

1.2 Accompanying Documents

This document, *Best Practice Guide for Sharing Vital Attributes in Healthcare*, is the fourth in a series of Healthcare specific documents intended to support the community in providing high-quality and trusted data that is foundational to basic healthcare processes and transactions. The preceding documents listed here serve to lay a strong foundation for healthcare trading partners wishing to share data and considering GDSN as a primary data sharing method.

<u>GS1 Healthcare US: Quick Start Guide for Implementing GDSN in Healthcare</u>

This document provides a brief overview of the steps and resources needed for a successful implementation of the GDSN for medical device and/or pharmaceutical products. This Quick Start Guide serves as a starting point to other GS1 Healthcare US GDSN documents.

Creating the Case for Trusted Data: Attribute Lists and Implementation Insights from Three Healthcare Business Process Cases Using GDSN

The purpose of this document is to:

- Identify the GDSN attributes recommended to support three healthcare use cases
- Offer insight and guidance about key topics for GDSN implementation
- Recommend next steps to help drive implementation of the GDSN in U.S. healthcare to support their need for quality product information.

<u>GS1 Healthcare US: Getting Started with GDSN</u>

This document provides a high-level resource to help healthcare organizations jumpstart their GDSN implementation efforts. The document outlines the key tasks that most companies will find necessary for a successful implementation, shares learnings, and explains the recommended processes established by other companies in their deployment of the GDSN.

Additionally, GS1 US recognizes that data quality depends on strong data governance practices. To that end, we believe that organizations wishing to share, consume, and use data should ensure that there are strong data governance fundamentals in place. The following resources are suggested to assist in the development of data management standard operating procedures and can be found on the GS1 US Website at: <u>https://www.gs1us.org/dataguality</u>



- Data Governance Best Practice Guidance
- **GS1 US National Data Quality Playbook**

1.3 Who Will Use this Document?

Both data sources and data recipients will benefit from using this document. Business users who are charged with master data management, procurement, regulatory compliance, and data governance may use this document. Additionally, it can serve to supplement the formal GS1 GDSN standards with additional guidance. IT resources within manufacturers, providers, and solution providers may use this information to support the sharing and/or consumption of data about healthcare products. This document is aimed primarily at business users who need to understand and execute on the data content.

1.4 Scope of this Document

The scope is the core data defined by the workgroup as the attributes needed to execute basic healthcare supply chain functions such as product identification, order to cash, and traceability as well as scanning at the point of care. This document may be updated as additional use cases or needs are identified.

Additionally, the workgroup felt that providing references for other required GUDID data elements would be beneficial to industry. To accommodate this, 11 data elements were added to the scope of this guidance document that were not part of the vital attributes business use cases exercises. You will find these additional data elements listed in Section 3.5.



2 Foundational Topics

2.1 Element Naming in GDSN

All **Module**, **Class**, **and Code List names** used in the GDSN Schema have no spaces, and all words in the name are capitalized. For example:

- TradeItemDescriptionModule
- AllergenInformation
- LevelOfContainmentCodeList

All **attribute names** used in the GDSN Schema have no spaces, and all words in the name are capitalized with the exception of the first word. For example:

- brandName
- tradeItemDescription

Note: See section 2.5 regarding Global Data Dictionary for accessing information about an attribute's definition, cardinality, and schema.

2.2 Cardinality Terminology for Attributes

For data synchronization, attributes have a characteristic which details if the attribute must be populated or not. This characteristic is called "cardinality." While the GDSN standards specify the baseline cardinality of the attributes overall, the GS1 Healthcare US Initiative has analyzed and supplemented the cardinality of attributes over and above that assigned by GDSN where appropriate for meeting the needs for the basic business use cases in scope for the healthcare industry. For example, the GDSN may specify an attribute as optional, but the Initiative may have determined that the attribute should be populated for a specific healthcare use case. This determination does not prescribe any need or eliminate the ability to require population of any attribute by a Data Recipient.

The cardinality of each attribute currently in scope in this document, with the exception of the attributes covered in Section 3.6 pertaining to GUDID, is listed in the <u>Creating the Case for Trusted Data:</u> <u>Attribute Lists and Implementation Insights from Three Healthcare Business Process Cases</u>. Cardinality term definitions are provided below.

- **GDSN Mandatory:** Attribute must be populated in order to load and/or share data via GDSN
- **Required:** Attribute is required to support the business process
- Required/Conditional: Attribute is required to support the business process but only if it is applicable to the product
- **Recommended:** Attribute is helpful to trading partners in support of the business process

2.3 Code Lists

The GDSN utilizes GS1 defined code lists as well as externally managed code lists (e.g., FDA.gov, ISO, etc.). Code lists used in the GDSN may be managed outside of the schema due to both frequency of update and requirements that vary between target markets.



There are several externally managed code lists, which are used in several areas of the schema to provide code values. The table below lists some of the most frequently used managed code lists for healthcare attributes.

Code List	Comments			
	<u>https://www.gs1.org/standards/gpc/access-</u> gpc-standards			
GPC Code (global product category)	The GS1 GPC is a system that gives buyers and sellers a common language for grouping products in the same way, everywhere in the world.			
ISO 3166-1 Country Code	https://www.iso.org/obp/ui/#search			
FDA Dosage Forms	<u>https://www.fda.gov/industry/structured-</u> product-labeling-resources/dosage-forms			
additionalClassificationCategoryCode	https://www.unspsc.org/			
GDSN Code List Document	https://www.gs1.org/standards/gdsn/current- standard			
 UoM (unit of measure), MeasurementUnitCode_GDSN 				
TradeItemUnitDescriptorCode				
 AdditionalTradeItemIdentificationTypeCode 				
 DataCarrierTypeCode 	GS1 maintains a periodically updated spreadsheet known as the GDSN Code List			
SerialNumberLocationCode	Document which contains all of the GS1 code			
TradeItemDateOnPackagingTypeCode	lists and their values. A specific code list and its values can be viewed by filtering on the			
MeasurementUnitCode_GDSN	Code List name in the first column.			
AdditionalTradeltemClassificationCodeListCode				
PackageTypeCode				
 PackagingMarkedFreeFromCode 				

2.4 GS1 Attribute Definitions for Business

<u>The GS1 Attribute Definitions for Business (ADB)</u> provides additional clarity to existing technical standards. Business-friendly names, definitions, examples, and usage statements simplify meaning and usage of standard attributes for business users and communities.



2.5 Global Data Dictionary

<u>The GS1 Global Data Dictionary (GDD)</u> is a repository of the data elements defined across all GS1 Standards. Each vital attribute discussed herein is headed by its common name followed by the GDSN name in parentheses. For the technical specifications of each attribute, please refer to the Global Data Dictionary.



3 Sharing Vital Attributes for Healthcare

While conducting our business process exercises in the development of <u>Creating the Case for Trusted</u> <u>Data: Attribute Lists and Implementation Insights from Three Healthcare Business Process Cases</u> a vitally important and impactful learning from those exercises was that, even once stakeholders agreed on what attributes needed to be shared to facilitate basic business processes, stakeholders often lacked the infrastructure in people, process, and technology to support robust data sharing with their trading partners. Additionally, variability in the content and format of data shared about individual attributes leads to inconsistency and unreliability of information across industry.

In order to be successful in establishing a meaningful and sustainable data sharing environment, trading partners need to make appropriate investments in process development, technology, and systems as well as training and personnel to support master data management. The following areas of focus were identified in the aforementioned exercises:

- Master data management
- Attribute mapping and interfaces
- Systems preparedness and mapping
- Establishment of a data team
- Data quality and strong data governance processes
- Trading partner collaboration

Throughout the course of our previous workgroup activities, we also learned that very consistent lists of core attributes needed to support healthcare uses cases are and have been available to support industry for many years. The issue is that industry has not collectively embraced or leveraged these recommendations, and trading partners have inconsistent format requirements for the attributes they do attempt to share. In the sections that follow, the Data Quality & Value of Trusted Data workgroup seeks to clarify best practices for sharing information about the critical data elements previously identified for industry. These best practices, if embraced and employed by data sources and data recipients, will support the completeness, accuracy, and consistency characteristics of trusted data across all industry stakeholders.

Note: To help users of this document better understand the best practice recommendations being made for each attribute, we will use several hypothetical examples of healthcare-related products. These examples are for illustrative purposes only and the accompanying attribute tables do not represent the only options for sharing data about healthcare products.

Note: For clarification, the use of "GTIN A", "GTIN B", etc. in this document is intended to show that a unique GTIN is assigned at this packaging level for this specific product example. "GTIN A" or "GTIN B" are not indicative of the same GTIN *across* the illustrative examples.

Note: In the attribute section headers below, we have noted the following: Common Name as defined in the <u>GS1 Global Data Model</u> and the GDSN attribute name in parentheses. With respect to cardinality, this is defined based on the recommendations as determined by industry and outlined in <u>Creating the Case for Trusted Data: Attribute Lists and Implementation Insights from Three Healthcare</u> <u>Business Process Cases</u> and is specific to these healthcare best practice recommendations only.



3.1 Attributes for Product Validation

At a minimum, trading partners will need to ensure that they are aligned on a specific product before sharing more robust information about that product. The following six attributes establish a solid foundation for sharing consistent data.

3.1.1 GTIN (gtin)

The global number that uniquely identifies a product and its various packaging levels (e.g. item, case, pallet) physical or non-physical; trade item identifier.

This field should contain the Global Trade Item Number (GTIN) in 14-digit format. A GTIN may be an 8-digit, 12-digit, 13-digit, or 14-digit string. However, the GTIN should always be stored in a database as a 14-digit number filled in with leading zeroes up to 14 digits. Additional information regarding GTIN formats may be found in the <u>GS1 Healthcare GTIN Allocation Rules Standard</u> and <u>GS1 General Specifications.</u>

3.1.2 Brand Name (brandName)

The name provided by the brand owner that is intended to be recognized by the consumer as represented on the product.

- GS1 Guidance: This should be the most recognizable brand on the package/trade item. If there is no brand on the package/trade item, this should be the brand name under which the item is sold.
- In the absence of a brand use 'unbranded", do not use the company name. In a combination package (ie kit) containing more than one brand, use "mixed". Either "unbranded" or "mixed" should be aliased/mapped to "N/A" in the GUDID Brand Name field.
- For pharmaceuticals, use the proprietary name.

3.1.3 **Product Description (tradel temDescription and additionalTradel temDescription)**

An understandable and useable description of a product using a combination of key elements necessary to communicate to the industry to help define the product.

- Primary Supply chain (long) descriptions shared between trading partners should use the tradeItemDecription attribute and be 200 characters or less as many data recipient systems have a limited field length for description.
- Except for units of measure (UoM), abbreviations should not be used unless necessary to meet the field length recommendation and should, if used, follow recommended abbreviation guidelines. If the event abbreviation is required, a complete unabbreviated description should also be populated to the GDSN 'additionalTradeItemDescription' field. If abbreviation is not required, the value in tradeItemDescription should also be used to populate additionalTradeItemDescription. This will accommodate data recipients who utilize larger field lengths, such as the US FDA's GUDID. In any case, both tradeItemDescription and additionalTradeItemDescription should be populated by data publishers due to the variability in downstream recipient's field lengths. Data publishers should consult with their data pools on managing these descriptions.



Punctuation should be limited to specified necessary special characters (mathematic/scientific).

Table 3-1 Special Characters to Avoid					
	&	Ampersand			
	,	Apostrophe			
	*	Asterisk			
	@	At			
	[]	Brackets			
	:	Colon			
	\$	Dollar			
	{}	Curly Brackets			
Special characters can create	=	Equal Sign			
data sharing and EDI issues	!	Exclamation Point			
<u>Do not use</u>	^	Insert/Caret			
	#	Number			
	()	Parenthesis			
		Pipe			
	?	Question Mark			
		Quotes			
	;	Semi-colon			
	~	Tilde			
	_	Underscore			

 Table 3-1
 Special Characters to Avoid



Use of mathematical and scientific characters, when necessary, is allowed.

		Decimal point (as a decimal only, always preceded by an integer or 0, ie .2 becomes 0.2 and .02 become 0.02)
Mathematical and scientific	_	Hyphen/Dash
characters Only use when necessary	%	Percentage
	+	Plus
	1	Slash

Table 3-2 Mathematical and Scientific Characters

- Do not add unnecessary spaces 0.5%, not 0.5%
- Use '-' to designate fractions of a whole where use of decimal system is not possible
 - Preferred = 5.5, but if fraction required then 5-1/2 not 5 1/2 or 51/2
- Medical Device Descriptions should be formatted in the following order:
 - Noun
 - Descriptors in Order of Importance
 - 1. Application/Use
 - 2. Trademark or Brand (if applicable)
 - 3. Dimensions
 - 4. Refill/Replacement/Substitute
 - 5. Single Use/Reprocessed/Disposable
 - 6. Sterile/Non Sterile
 - 7. Latex Content
 - 8. Material
 - 9. Other Attributes
 - Size
 - Color
 - Packaging string down to unit of use when the identifier is associated with a specific package such as in GDSN with the net quantity of the unit of uses
- Descriptions for pharmaceutical items should match First Data Bank label names



- Product descriptions associated with specific packages (such as in GDSN) should include a complete packaging string from the package in question down to the base package or unit of use, whichever is lower. The packaging string should utilize ANSI UoM abbreviations and quantity for each packaging level. For example, the packaging string for a case of 6 boxes of 12 vials of 25 glucose test strips would be:
 - CA/6, PK/12, VI/25, 1EA NET QTY 1800

The base unit or unit of use (lowest level) should be specified, not assumed. EA (for each) should be used when ANSI does not have an abbreviation as in the example "test strip".

If there is standard unit of use or dosage for a product packaged in a bulk multiple unit of use or multi-dose container (ie a multi-dose vial of a pharmaceutical), the net quantity in the description should reflect the total discrete quantity and the number of units or use or doses as well as the standard dose. If the unit of use or dosage is not standard, the description should indicate where the usage/dosage information can be found. For example, the packaging string for a case of 10 boxes of 6 5ml vials of flu vaccine with a standard dose of 0.5 ml would be:

• CA/10, PK/6, VI/5ml NET QTY 300ml = 600 doses of 0.5ml

An injectable pharmaceutical in the same packaging configuration with variable dosing, for instance based on patient weight, would have the following packaging string:

• CA/10, PK/6, VI/5ml NET QTY 300ml see package insert for dosage information

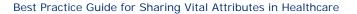
Note: Data publishers should recognize that many healthcare providers utilize both a long description and a "short description" limited to 30 characters. The Joint Commission requires that a hospital ensure the standardized use of approved symbol and abbreviations across the hospital. As there is no industry standard list of approved abbreviations, this can prove challenging for a healthcare provider dealing with hundreds - if not a thousand or more - suppliers potentially utilizing differing abbreviation protocols. Unless or until the industry can develop comprehensive abbreviation standards, it is more practical for data publishers to provide complete unabbreviated descriptions and have data recipients develop short descriptions when needed based on their protocols.

Data publishers should recognize that some healthcare provider's data utilize clinical descriptions for some products. Data providers may want to provide a clinical description for products where such a description might provide additional benefit. Guidelines for clinical descriptions are out of scope for this work group. If they are provided, the GDSN attribute 'additionalTradeItemDescription' should be used.

3.1.4 Global Product Category (gpcCategoryCode)

The code used to group products based on their essential properties and characteristics according to the GS1 Global Product Classification (GPC).

- 8-digit field
- GS1 provides a four-tier hierarchy for product classification, which is currently not commonly used in US Healthcare. However, a GPC code is required for GTIN registration and verification. Healthcare manufacturers should, at a minimum, utilize either 10005844 (medical devices) or 10005845 (drugs). The complete list of GPC codes for healthcare can be found online at <u>GS1 GPC Standards</u>.





3.1.5 Net Content and Unit of Measure (netContent and CodeListTransactionalMeasurementUnitCode)

The quantity (or quantities) of the product contained in the package along with its unit of measure typically printed on the label for the country or market where the product is sold.

Net Content Principles – It is important to recognize that within the healthcare industry product information is utilized beyond the supply chain and that product information is potentially tracked to individual patients, included in patient records, and used for product recalls as well as product safety, effectiveness, and outcomes studies. Accordingly, net content, unit of measure (UoM), and complete packaging hierarchy information regarding medical products and pharmaceuticals are very important to healthcare providers for both supply chain and clinical purposes. These attributes are important to their understanding of the quantity of unit of use items in a specific package, as well as within an order, for allocating supply costs to clinical procedures and patient care episodes, planning efficient order quantity options, ensuring patient safety, and understanding potential waste for products distributed with a unit of use quantity greater than one. As such, net content, UoM, and packaging hierarchy are valuable inputs in getting the right product to the right patient at the right time.

These recommendations are intended to provide guidelines that will help lead to consistency in communication and the ease of understanding of the packaging and net content information for both suppliers and providers while complying with regulatory requirements. That, in turn, should result in greater efficiencies, fewer errors, and lower costs for all parties. While there is significant variability in how different systems manage and store net content and packaging information, the objective is to communicate within industry as simply as possible the actual number of devices or amount of usable product within any particular package and the packaging hierarchy/family (children and/or parents) associated with that product. To this end, we recommend that suppliers include a complete packaging string and net quantity as the last component of each package's long description (see "Product Description" best practice recommendation above).

- Within GDSN Net Content and UoM are two separate attributes, Net Content is a numeric value and UoM a code value from GS1 GDSN Code List Document (Mar 2020). Data publishers must populate both attributes within GDSN.
- Net Content and Unit of Measure should be populated beginning with the base package (GDSN)/Primary DI# (FDA GUDID). This is the lowest level package intended for resale or distribution in GDSN and has a full UDI for the GUDID. The net content of any package should reflect the total number of units of use in that package.

GDSN allows for multiple net content & UOM for trade items. In cases where a trade item is packaged in bulk quantities and the unit of use or dosage is known and fixed, it is recommended that both net quantity measures be populated. See below for some common examples.

Net Content Examples:

Glucose Strips - Case of 6 boxes of 12 vials of 25 glucose test strips: Net Content of vial = 25EA,

Net Content of box = 300EA, Net Content of case = 1800EA

- Exam Gloves 100 box, 12 boxes per case: Net content of box = 100EA, Net content of case = 1200EA
- Surgical Gloves Sterile Disposable Pairs, 200 pairs/case: Net content of case = 200PR



- Aspirin Case of 12 bottles of 250 325mg: Net content of bottle = 250EA, Net content of case = 3000EA
- Flu Vaccine Case of 10 boxes of 6 5.0 ml vials of flu vaccine with a standard dose of 0.5 ml: Net Content of vial = 5ml or 10 doses of 0.5ml, Net Content of pack = 30ml or 60 doses of 0.5ml, Net Content of case = 300ml or 600 doses of 0.5ml

Note: The FDA's GUDID utilizes a different methodology to manage package quantity information. This consists of "Device Count" which is the number of medical devices in the base package and "Quantity per Package" which is the <u>number of packages with the same Primary DI or Package DI within a</u> <u>given packaging configuration.</u> If the "Device Count" for the base package is greater than one, the FDA requires a 'Unit of Use DI Number' which is "An identifier assigned to an individual medical device when a UDI is not labeled on the individual device at the level of its unit of use (UoU). Amongst other uses, UoU DIs are used to associate device utilization with patients. UoU is a term not commonly used outside of healthcare. GS1 has created an attribute 'uDIDDeviceCount' to store the GUDID Device Count attribute associated with the base package/primary DI. When the 'uDIDDeviceCount is > 1, GDSN requires implementation of "component attribution" to communicate information about parts of a trade item. Each component of the trade item is assigned a componentNumber. A base unit containing more than one UoU of the same device would have just one component and the componentIdentification would be populated with the unit of use DI (virtual GTIN) for the GUDID. This component attribution approach is also used to handle similar situations such as Single Dose or Level Below the Each.

Mapping - Blood Glucose Test Strips, vial of 25, box of 12 vials, case of 6 boxes -1800 strips

DI (GTIN)	Description	Package	Net Content	LloM	Packaging String	
0614141000037	Test Strip Blood Glucose	EA	1	EA		
0614140000036	Test Strip Blood Glucose VI/25	VI	25	EA	VI/25, 1/EA NET QTY 2	25
0614140000033	Test Strip Blood Glucose BX/12 VI/25	BX	300	EA	BX/12,VI/25,1/EA NET QT	Y 300
0614140000 30	Test Strip Blood Glucose CS/6 BX/12 VI	/25 CA	1900	EA	CA/6,8X/12,VI/25,1/EA NET	QTY 1800
1		Packaging Le Product Nar Global Trade	ne Blood glu		PACK_OR_INNER_PACK st strips Blood glucose test strips	Blood glucose test stri
			tem 20614	4141000	030 10614141000033	00614141000036
-		Number		8118	81/4	0.5
`compon	entIdentification'	Device Cou		N/A	N/A	25
	se (virtual) GTIN	Child GT!	and the second se	4141000	033 00614141000036	N/A
Unit Of U	se (virtual) GIIN	Quantity of N Lower Level T Item		8	12	N/A
		100111				

Note: This document contains multiple code sets which are updated frequently. The code list that is traditionally used for trade item etc. UoMs is MeasurementUnitCode_GDSN. Also, UoM is not specifically listed but is shown as 'CodeListTransactionalMeasurementUnitCode'. Within Healthcare, it is recommended that data publishers utilize the ANSI X12 Standards for the actual UoM and UoM abbreviations. Unfortunately, the GS1 'CodeListTransactionalMeasurementUnitCode' does not map 100% to the ANSI X12 standard. Data publishers may come across a situation where the ANSI measurement does not have an exact match in the code list. If that situation occurs, we recommend that the data publisher consult with their GS1-certified data pool on how to address that particular situation.



3.1.6 Target Market/Country of Sale (targetMarketCountryCode)

The code representing the country where the physical or non-physical product is intended to be sold.

- The 3-digit code of ISO 3166-1, International Standard for country codes and codes for their subdivisions, is used within GDSN to indicate countries, dependencies, and other areas; or one of the following GS1 additional country codes such as:
 - 001 World or Global Market
 - 097 European Union

- D_A Development Assistance
- NON_EU Non European Countries

- US United States
- FR France

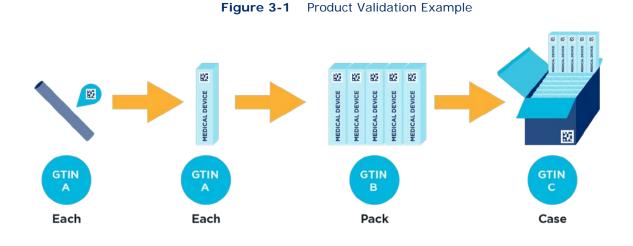


 Table 3-3
 Product Validation Attributes with Example Values

Common		GUDID	Packaging Level						
Name	GDSN Attribute	Data Element	Unit of Use	Base Unit	Inner Pack	Case			
Product Description	tradeItemDescription	Device Description	n/a	Flow tube disposable non-sterile 1EA	Flow tube PK/5 1EA NET QTY 5	Flow tube CA/7 PK/5 1EA NET QTY 35			
Product Identifier, GTIN	globalTradeItemNumber (GTIN)	DI (device identifier)	n/a	GTIN A	GTIN B	GTIN C			
Brand Name	brandName	Brand Name	n/a	unbranded	unbranded	unbranded			
Global Product Category (GPC) Code	gpcCategoryCode	n/a	n/a	10005844	10005844	10005844			
Net Content & UoM	netContent (& UOM)	Device Count	n/a	1EA	5EA	35EA			



		Quantity per Package				
Country of Sale/Target Market	targetMarketCountryCode	n/a	n/a	001	001	001

3.2 Attributes for Procurement & Payment

In addition to the attributes in Section 3.1, the following attributes have been deemed required by healthcare trading partners to support Procurement and Payment.

3.2.1 Unit Descriptor (TradeItemUnitDescriptorCode)

The code that describes the product's packaging level.

- The GDSN attribute tradeItemUnitDescriptor is chosen from a GS1 maintained code list of seven values used to describe the GTIN hierarchy level. Hierarchy is used to establish a link between different levels of a product logistical chain.
- This hierarchy has its roots in the grocery and retail industries in which terms "each" and "base unit" are often used interchangeably. As such, the BASE_UNIT_OR EACH historically denotes the lowest traded package level. This level might contain more than one single unit/unit of use. In healthcare, the industry is working to be able to track products below this hierarchical level to the individual patient record. Accordingly, the GS1 Healthcare GTIN Allocation Rules Standard recommends that "for medical devices, there is only a single level of a product below the lowest packaged level to ensure accuracy in the supply chain and ensure traceability". The data quality workgroup extends this recommendation to pharmaceuticals and also recommends that if the unit of use is marked with an identifier (whether human or machine readable or both), it should be considered the base unit.
- Note, however, the workgroup does not advise changing existing hierarchies to meet this recommendation if that would trigger a requirement to create new GTINs, which would cause a different set of supply chain challenges. This recommendation should be used for new products and when another circumstance results in changes to the hierarchy or GTINs.

Code Value	Name	Definition	Change Date	Version	Status
BASE_UNIT_OR_EACH	Base Unit or Each	The lowest level of the item hierarchy intended or labeled for individual resale.		1	CURRENT
CASE	Case	A standard trade item shipping unit that contains a single or multiple GTINs. Includes an ${\rm 1/2}$ or ${\rm 1/4}$ pallet and an ${\rm 1/2}$ or ${\rm 1/4}$ pallet.		1	CURRENT
DISPLAY_SHIPPER	Display Shipper	A display, a shipper. May have a "PL" parent. May have (CA or EA) children in multiple instances. It may be Orderable and can be a Consumer Unit.		1	CURRENT
MIXED_MODULE	Mixed Module	A unit load that is a "display ready pallet" that may contain a single GTIN or several unique GTINs that is intended to go directly to the selling floor		1	CURRENT
PACK_OR_INNER_PACK	Pack or Inner Pack	A logistical unit between case and each. This may be a consumable innerpack (i.e. Carton of Cigarettes) or it may be simply a logistical pack (i.e. Dozes of toothbrushes).		1	CURRENT
PALLET	Pallet	A unit load that contains a single or multiple GTINs Includes box pallet		1	CURRENT
TRANSPORT_LOAD	Transport Load	Trade item above the pallet level used for transporting trade items. For example truck load, container, rail car, ship, etc.		1	CURRENT

Note: When the product hierarchy includes a pallet as an orderable unit, additional data elements may be required to be shared with trading partners.



3.2.2 Name of Information Provider (partyName [info provider]) The name of the party providing the product information.

- 1 to 35 character text field
- This field is to contain the name of the entity publishing the information.

3.2.3 Global Location Number of Information Provider (gln [info provider])

The Global Location Number (GLN) used to uniquely identify the party providing the product information.

- 13 digits
- This field is to contain the GLN of the entity publishing the information.

3.2.4 Orderable Unit Indicator (isTradeItemAnOrderableUnit)

The indicator that specifies that the information provider considers the product can be ordered.

This is a Boolean True/False response dependent upon the publisher and recipient.

Example: A manufacturer who does not sell direct to providers would respond True for a distributor but False to the provider/end user. The distributor publishing to providers would respond True for package sizes the providers could order from the distributor.

3.2.5 Base Unit Indicator (isTradeItemABaseUnit)

The indicator that specifies this product does not contain another intended sellable unit. (NOTE: for healthcare products there could be a level below this base unit. See "Unit of Use")

- Boolean True/False
- Conceptually, the base item should be thought of as the lowest level of packaging intended for sale or distribution, <u>including internal distribution at the provider level</u>.
- GDSN An indicator identifying the trade item as the base unit level of the trade item hierarchy
- GUDID An identifier that is the main (primary) lookup for a medical device and meets the requirements to uniquely identify a device through its distribution and use. The Primary DI would be located on the base package, which is the lowest level of a medical device containing a full UDI. For medical devices without packaging, the Primary DI number and full UDI may be on the device itself.

3.2.6 Additional Product Identification Code (AdditionalTradeItemIdentificationTypeCode)

The code indicating the type of Additional Product Identification used.



- Conceptually, the additional trade item identification is the Catalog number or the Model number of the product for medical devices. It should be the NDC in 10-digit format for pharmaceuticals.
- GS1 Code List: For medical devices use "SUPPLIER_ASSIGNED" when publishing Catalog Number. Catalog Number is preferred; however, if not available, use "MODEL_NUMBER" and publish Model Number in "additionalTradeItemIdentificationValue".
- For pharmaceuticals, the code is always the value FDA_NDC_10.

3.2.7 Additional Product Identifier (additionalTradeItemIdentificationValue)

An identifier, other than the GTIN, which provides an additional identification for the product.

- For medical devices, if "additionalTradeItemIdentificationCode" is SUPPLIER_ASSIGNED" then, "additionalTradeItemIdentificationValue" would equal Catalog #.
- If "additionalTradeItemIdentificationCode" is "MODEL_NUMBER" then, "additionalTradeItemIdentificationValue" would equal Model #.
- Catalog # is preferred and should be populated as the same number as the data source has in their system.
- For pharmaceuticals, the value should be the NDC in 10-digit format.

3.2.8 Manufacturer Name (party name [manufacturer name])

The name of the manufacturer.

- 1 to 35 character text field
- Manufacturer Name may or may not be the same as the Name of Information Provider. In instances
 where the Brand Owner controls a third-party manufacturer relationship, the Manufacturer Name may
 be the same as Brand Owner Name.



Note: Some regulations outside of US may impact this. Our scope is US.

3.2.9 Manufacturer GLN (gln [manufacturer])

The Global Location Number(GLN) that uniquely identifies the party who owns the manufacturing process of the product.

- 13-digit number
- This GLN should correspond to the entity named as Manufacturer.

3.2.10 Functional Name (functionalName)

Describes use of the product or service by the consumer. Should help clarify the product classification associated with the GTIN. Allows for the representation of the same value in different languages but not for multiple values.



Note: If the GPC code for "Medical Device" or "Pharma" is provided, then Functional Name is not GDSN Mandatory.

- There is a validation rule requiring that functionalName not be empty and many data consumers and downstream systems expect a value in this field. Therefore, we recommend that information providers include a simple noun descriptor such as syringe, bone screw, or glove in this field regardless of the GPC code. For pharmaceuticals, use the regulated product name.
- In food, this attribute will typically be used to communicate the 'commodity' (product family), such as 'oranges', 'grapes', 'chicken', 'beef', etc.

3.2.11 Number of Different Products (quantityOfChildren)

The number of different products, each with a unique GTIN, within this item.

- Value indicates the number of unique next lower-level trade items contained in a complex trade item.
 A complex trade item contains at least two different GTINs.
- In the example of a case of 6 boxes of 12 vials of 25 glucose test strips, the quantity of children in all examples is 1 as each package contains only unique children. However, in the example of a OR Procedure Kit, the "quantity of children" would be the number of unique components of the kit.

3.2.12 Total Count of All Products (totalQuantityOfNextLowerLevelTradeItem)

This represents the Total quantity of next lower-level trade items that this trade item contains NOTE: Only applies if trade item contains unique GTIN(s) such as a kit containing multiple items.

This represents the total quantity of all next lower level trade items that this trade item contains. This could be a case of a single product, a multi-pack, a pallet of cases of a single product, and/or a pallet of different products (different cases). The information is used by a buyer and/or consumer to understand what type of product they are receiving; also used for inventory/warehouse management. For example, a First Aid Kit First consisting of 1 pair of scissors, 2 rolls of tape, and 3 packs of bandages would have a quantityOfChildren of 3 (scissors, tape and bandages) and a totalQuantityOf NextLowerLevelTradeItem of 6 (1+2+3).

3.2.13 Child Trade Item (tradeItemIdentificationOfNextLowerLevelTradeItem [GTIN])

The GTIN of the trade item in the item hierarchy level immediately below the trade item in question.

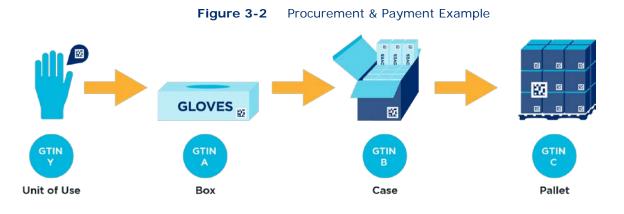
- Only applies if answer to "Is Trade Item a Base Unit?" = NO
- Implicitly, this would also not apply to a Unit of Use GTIN.



3.2.14 Count of Each Specific Product (quantityOfNextLowerLevelTradeItem)

The count of each specific product within this item. This represents the Total quantity of each of the unique next lower level trade items that this trade item contains. NOTE: Applies if a value is provided for "Next Lower Level GTIN"

The quantity of each child trade item contained by the parent trade item. The child trade item must be in the hierarchy level immediately below the parent trade item. If the parent trade item contains more than one GTIN children, then each of those children will have its own 'quantityOfNextLowerLevelTradeItem'. For example, a First Aid Kit First consisting of 1 pair of scissors, 2 rolls of tape, and 3 packs of bandages would have a value of 1 for the scissors, 2 for the tape, and 3 for bandages.





Common	GDSN Attribute	GUDID Data	Packaging Level			
Name	GDSN Attribute	Element	Unit of Use (single glove)	Base Unit	Case	Pallet
Product Description	tradeItemDescription	Device Description	Gloves, Nitrile, Exam Grade, LG, Disposable BX/100 NET QTY 1	Gloves, Nitrile, Exam Grade, LG, Disposable BX/100 NET QTY 100	Gloves, Nitrile, Exam Grade, LG, Disposable CA/10 BX/100 NET QTY 1000	Gloves, Nitrile, Exam Grade, LG, Disposable PL/70 CA/10 BX/100 NET QTY 70000
Product Identifier, GTIN	globalTradeItemNumber (GTIN)	DI (device identifier)	GTIN Y	GTIN A	GTIN B	GTIN C
Brand Name	brandName	Brand Name	n/a	unbranded	unbranded	unbranded
Global Product Category (GPC) Code	gpcCategoryCode	n/a	n/a	10005844	10005844	10005844
Net Content & UoM	netContent (& UOM)	Device Count / Quantity per Package	n/a	100 EA	1000 EA	70000 EA
Country of Sale / Target Market	targetMarketCountryCode	n/a	n/a	001	001	001
Child Trade Item	tradeItemIdentificationOf NextLowerLevelTradeItem (GTIN)	n/a	n/a	n/a	GTIN A	GTIN B



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Common	GDSN Attribute	GUDID Data Element	Packaging Level					
Name			Unit of Use (single glove)	Base Unit	Case	Pallet		
Count of Each Specific Product	quantityOfNextLowerLeve ITradeItem	n/a	n/a	1	10	70		
Unit of Use DI	componentIdentification	Unit of Use DI Number	n/a	GTIN Y	n/a	n/a		
Unit Descriptor	TradeItemUnitDescriptorC ode	n/a	n/a	BASE_UNIT_OR_ EACH	CASE	PALLET		
Name of Informatio n Provider	partyName	n/a	n/a	Healthcare Products Inc	Healthcare Products Inc	Healthcare Products Inc		
GLN of Informatio n Provider	gln (info provider)	n/a	n/a	0614141000005	0614141000005	0614141000005		
Orderable Unit Indicator	isTradeItemAnOrderableU nit	n/a	n/a	FALSE	TRUE	TRUE		
Base Unit Indicator	isTradeItemABaseUnit	n/a	n/a	TRUE	FALSE	FALSE		
Additional Product Identifier Code	AdditionalTradeItemIdenti ficationTypeCode	Version or Model Number	n/a	SUPPLIER_ASSI GNED	SUPPLIER_ASSI GNED	SUPPLIER_ASSI GNED		
Additional Product Identifier	additionalTradeItemIdenti ficationValue	Version or Model Number	n/a	Fictitious Catalog# A	Fictitious Catalog# B	Fictitious Catalog# C		
Manufactur er Name	partyName (mfg name)	n/a	n/a	Healthcare Products Inc	Healthcare Products Inc	Healthcare Products Inc		
Manufactur er GLN	gln (mfg)	n/a	n/a	0614141000005	0614141000005	0614141000005		
Functional Name	functionalName	n/a	n/a	Exam Glove	Exam Glove	Exam Glove		
Number of Different Products	quantityOfChildren	n/a	n/a	1	1	1		
Total Count of All Products	totalQuantityOfNextLower LevelTradeItem	n/a	n/a	1	10	70		



3.3 Attributes for EPCIS for Drug Supply Chain Security Act

In addition to the attributes in section 3.1 and 3.2, the following attributes have been deemed required by healthcare stakeholders to support EPCIS for the Drug Supply Chain Security Act (DSCSA). These attributes successfully supported the use of EPCIS for traceability of pharmaceutical products in a proof of concept exercise conducted by pharmaceutical supply chain stakeholders.

3.3.1 Consumer Unit Indicator (isTradeItemaConsumerUnit)

The indicator that specifies the product can be purchased or, in some trade channels (e.g., food service, healthcare), used by the consumer.

- Boolean True/False
- Identifies whether the trade item is to be taken possession of, or to be consumed or used by, an end user or both, as determined by the manufacturer. The end user could be, but is not limited to, a consumer as in items sold at retail, or a patient/clinician/technician in a healthcare setting, or an operator for foodservice such as restaurants, airlines, cafeterias, etc.

3.3.2 Invoice Unit Indicator (isTradeItemAnInvoiceUnit)

The indicator identifying that the information provider considers the trade item as an invoiceable unit.

- Boolean True/False
- An indicator identifying that the information provider will include this trade item on their billing or invoice. This may be relationship dependent based on channel of trade or other point to point agreement.

3.3.3 Shipping Unit Indicator (isTradeItemA DespatchUnit)

The indicator identifying that the information provider considers the trade item as a shipping unit.

- Boolean True/False
- An indicator identifying that the information provider considers the trade item as a dispatch (shipping) unit. This may be relationship dependent based on channel of trade or other point to point agreement.

3.3.4 Variable Measure Indicator (isTradeItemAVariableUnit)

The indicator that specifies the product content is variable (ie not a fixed quantity).



- Boolean True/False
- Indicates that an article is not a fixed quantity, but that the quantity is variable. Can be weight, length, volume, trade item is used or traded in continuous rather than discrete quantities

3.3.5 Effective Date (effectiveDateTime)

The date/time when the product information becomes effective.

- This is the date and time at which the associated product information becomes effective. Used by the data recipient to determine the date/time when the product information should be applied in their system. Data recipients should not apply the product information prior to the effective date and time.
- Check with data pool regarding preferred format

3.3.6 End Availability Date Time (endAvailabilityDateTime)

The date/time when the product is no longer available for order from the information provider/seller.

- The date from which the trade item is no longer available from the information provider
- Check with data pool regarding preferred format
- If there is no end date, this field can be left blank. It is expected that for pharmaceutical products this field will not be left blank. To avoid confusion for products that have no end date, it is recommended the data publisher use 12/31/9999 so that the data recipient knows affirmatively that the end availability date is indefinite, and the field was not inadvertently left blank.

3.3.7 Dosage Form Type (dosageFormType)

The code that provides a description of the physical form of a medication or dietary supplement.

- Intended to represent the physical form of a medication. Data publishers should utilize the 'dosageFormTypeCodeReference' populated with the FDA code from the FDA Dosage Forms code table at: <u>https://www.fda.gov/industry/structured-product-labeling-resources/dosage-forms</u>
- Data publishers should consult with their data publishers and refer to the Pharmaceutical Information Module of the most recent <u>GDSN Trade Item Module Library Business Message Standard</u> to assure data recipients can display the SPL term (AEROSOL, CAPSULE, GEL, PILL, TABLET...) associated with the code.
- Additional information regarding use of GS1 Standards and the DSCSA may be found in <u>Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability Release 1.2</u>



3.3.8 Ingredient Strength (ingredientStrength)

Used to define the strength of each ingredient in a trade item or unit volume of non-food and beverage the trade items.

- Intended to define strength of each ingredient in a trade item or unit volume of non-food and beverage the trade items. The objective for pharmaceuticals is to communicate the strength or potency of the product including the unit of measure (for example, 60 mg, 25 ml). This should match the regulatory filing for the product.
- Pharmaceutical Serialization and Traceability Use Case Enable the sharing of pharmaceutical product information via the GDSN Release 1 specifies that the GDSN attribute 'ingredientStrength' be used to define the strength of each ingredient in a trade item or unit volume of non-food and beverage items.
- Data publishers should refer to the Nonfood Ingredient Module of the most recent <u>GDSN Trade Item</u> <u>Module Library Business Message Standard</u> and consult with their data pool on populating the appropriate attributes.

3.3.9 Data Carrier Type Code (DataCarrierTypeCode)

A code indicating the type of data carrier physically present on the trade item. NOTE: In US for pharmaceuticals, this is defined by regulation to be 2D DataMatrix. This attribute is therefore assumed for US target market but required for O-US.

- Identifies the barcode marked on the product or package; For example, linear versus DataMatrix.
- Codes can be found on the current <u>GDSN and Shared Code List</u>.
- For Pharma, a GS1 DataMatrix is expected, "GS1_DATA_MATRIX"
- For Med Devices, the data publisher should consult <u>GS1 US Healthcare Implementation Guide:</u> <u>Applying the GS1 System of Standards for U.S. FDA Unique Device Identification</u> Part 4 and the decision tree in Section 2.3.1-1.

3.3.10 Serial Number Location (SerialNumberLocationCode)

The location on the item or packaging of a serial number. A serial number is a code, numeric, or alphanumeric assigned to an individual instance of an entity for its lifetime.

- Identifies if the label or barcode includes a serial number.
- Codes can be found on the current <u>GDSN and Shared Code List.</u>
- Multiple codes are allowed if the serial number is marked in more than one location.



MARKED_ON_PACKAGING

MARKED_ON_PACKAGING_INSERT

MARKED_ON_TRADE_ITEM

NOT_MARKED

UNKNOWN

3.3.11 Has Batch Number (hasBatchNumber)

The indicator specifying whether the item has a batch or lot number.

- Boolean True/False
- Indicates if the label or the barcode includes Batch or Lot number

3.3.12 Trade I tem Date on Packaging Type Code (tradeI temDateOnPackagingTypeCode) The code indicating the type of date on the package to the buyer and consumer.

- Indicates if the label or barcode includes an *expiry date*
- Codes can be found on the current GDSN and Shared Code List
- For Pharma in US for DSCSA, "EXPIRATION_DATE" is expected

BAKED_FOR_DATE BAKED_ON_DATE

BEST_BEFORE_DATE

DISPLAY_UNTIL_DATE

EXPIRATION_DATE

FREEZE_BY

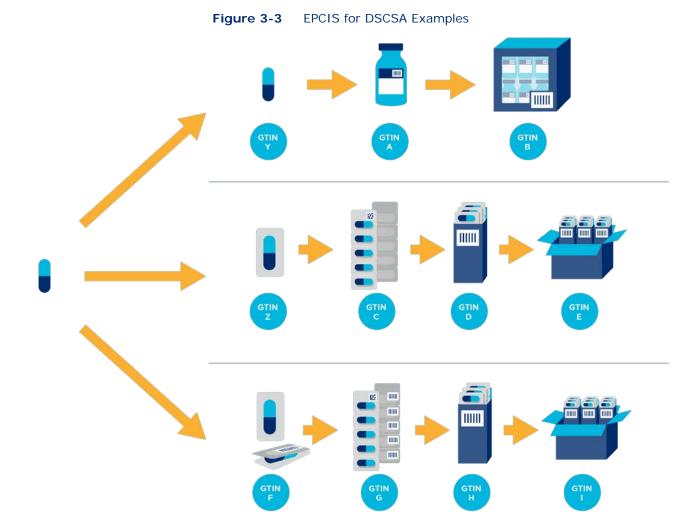
LAST_SALE_DATE

NO_DATE_MARKED

PACKAGING_DATE

PRODUCTION_DATE







		GUDID Data Element	Packaging Level				
Common Name	GDSN Attribute		Unit of Use	Base Unit	Inner Pack	Case	
Product Description	tradeItemDescription	Device Descriptio n	n/a	Generic Medication 100 mg Tablet BO/500 NET QTY 500	n/a	Generic Medication 100 mg Tablet CA/6 BO/500 NET QTY 3000	
Product Identifier, GTIN	globalTradeItemNumber (GTIN)	DI (device identifier)	GTI N Y	GTIN A	n/a	GTIN B	
Brand Name	brandName	Brand Name	n/a	unbranded	n/a	unbranded	
Global Product Category (GPC) Code	gpcCategoryCode	n/a	n/a	10005845	n/a	10005845	
Net Content & UoM	netContent (& UOM)	Device Count / Quantity per Package	n/a	500 EA	n/a	3000 EA	
Country of Sale / Target Market	targetMarketCountryCode	n/a	n/a	001	n/a	001	
Child Trade Item	tradeItemIdentificationOfNextLowerLevelTradeIte m (GTIN)	n/a	n/a	n/a	n/a	GTIN A	
Count of Each Specific Product	quantityOfNextLowerLevelTradeItem	n/a	n/a	n/a	n/a	500	
Unit of Use DI	componentIdentification	Unit of Use DI Number	n/a	GTIN Y	n/a	n/a	
Unit Descriptor	TradeItemUnitDescriptorCode	n/a	n/a	BASE_UNIT_OR_EAC H	n/a	CASE	
Name of Information Provider	partyName	n/a	n/a	Pharma Products Inc	n/a	Pharma Products Inc	
GLN of Information Provider	gln (info provider)	n/a	n/a	0614141000029	n/a	0614141000029	
Orderable Unit Indicator	isTradeI temAnOrderableUnit	n/a	n/a	TRUE	n/a	TRUE	
Base Unit Indicator	isTradeItemABaseUnit	n/a	n/a	TRUE	n/a	FALSE	
Additional Product Identifier Code	AdditionalTradeItemIdentificationTypeCode	Version or Model Number	n/a	FDA_NDC_10	n/a	FDA_NDC_10	
Additional Product Identifier	additionalTradeItemIdentificationValue	Version or Model Number	n/a	NDC A	n/a	NDC A	
Manufacturer Name	partyName (mfg name)	n/a	n/a	Pharma Products Inc	n/a	Pharma Products Inc	

Table 3-5EPCIS for DSCSA Attributes with Example Values 1 of 3 - Bottle of 500



Best Practice Guide for Sharing Vital Attributes in Healthcare

		GUDID Data Element	Packaging Level				
Common Name	GDSN Attribute		Unit of Use	Base Unit	Inner Pack	Case	
Manufacturer GLN	gln (mfg)	n/a	n/a	0614141000029	n/a	0614141000029	
Functional Name	functionalName	n/a	n/a	Generic Medication 100MG	n/a	Generic Medication 100MG	
Number of Different Products	quantityOfChildren	n/a	n/a	n/a	n/a	1	
Total Count of All Products	totalQuantityOfNextLowerLevelTradeItem	n/a	n/a	n/a	n/a	6	
Consumer Unit Indicator	isTradeItemAConsumerUnit	n/a	n/a	FALSE	n/a	FALSE	
Invoice Unit Indicator	isTradeItemAnInvoiceUnit	n/a	n/a	TRUE	n/a	TRUE	
Shipping Unit Indicator	isTradeItemADespatchUnit	n/a	n/a	TRUE	n/a	TRUE	
Variable Measure Unit Indicator	isTradeItemAVariableUnit	n/a	n/a	FALSE	n/a	FALSE	
Effective Date	effectiveDateTime	being researche d	n/a	2020-01- 01T04:00:00Z	n/a	2020-01- 01T04:00:00Z	
End Availability Date/Time	endAvailabilityDateTime	n/a	n/a	9999-12- 31T23:59:59Z	n/a	9999-12- 31T23:59:59Z	
Dosage Form Type	dosageFormTypeCodeReference	n/a	n/a	CAPSULE	n/a	CAPSULE	
Ingredient Strength	ingredientStrength	n/a	n/a	100 MG	n/a	100 MG	
Data Carrier Type Code	DataCarrierTypeCode	n/a	n/a	GS1_DATA_MATRIX	n/a	GS1_DATA_MATRIX	
Serial Number Location Code	SerialNumberLocationCode	Serial Number	n/a	MARKED ON PACKAGING	n/a	MARKED ON PACKAGING	
Has Batch Number	hasBatchNumber	Lot or Batch Number	n/a	TRUE	n/a	TRUE	
Trade Item Date on Packaging Code	tradeItemDateOnPackagingTypeCode	By Expiration Date	n/a	EXPIRATION_DATE	n/a	EXPIRATION_DATE	



Common	GDSN Attribute	GUDID Data Element	Packaging Level					
Name			Unit of Use	Level Below Base Base Unit (Card)	Box / Base Unit	Case		
Product Description	tradeItemDescription	Device Description	n/a	Generic Medication 100 mg Tablet CG/5 NET QTY 5	Generic Medication 100 mg BX/3 CG/5 NET QTY 15	Generic Medication 100 mg Tablet CA/12 BX/3 CG/5 NET QTY 180		
Product Identifier	globalTradeItemNumber (GTIN)	DI (device identifier)	GTIN Z	GTIN C	GTIN D	GTIN E		
Brand Name	brandName	Brand Name	n/a	Unbranded	unbranded	unbranded		
GPC Code	gpcCategoryCode	n/a	n/a	10005845	10005845	10005845		
Net Content	netContent (& UOM)	Device Count / Quantity per Package	n/a	5 EA; 1 CG	15 EA; 3 CG	180 EA; 36 CG		
Country of Sale / Target Market	targetMarketCountryCode	n/a	n/a	001	001	001		
Next Lower Level Package Identifier	tradeItemIdentificationOfNe xtLowerLevelTradeItem (GTIN)	n/a	n/a	n/a	GTIN C	GTIN D		
Quantity of next lower level package	quantityOfNextLowerLevelT radeItem	n/a	n/a	5	3	12		
Unit of Use DI	componentIdentification	Unit of Use DI Number	n/a	GTIN Z	n/a	n/a		
Unit Descriptor	TradeItemUnitDescriptorCo de	n/a	n/a	BASE_UNIT_OR_EACH	PACK_OR_INNER _PACK	CASE		
Name of Information Provider	partyName	n/a	n/a	Pharma Products Inc	Pharma Products Inc	Pharma Products Inc		
GLN of Information Provider	gln (info provider)	n/a	n/a	0614141000029	0614141000029	0614141000029		
Is Trade Item an Orderable Unit?	isTradeItemAnOrderableUni t	n/a	n/a	FALSE	TRUE	TRUE		
Is Trade Item a Base Unit?	isTradeItemABaseUnit	n/a	n/a	TRUE	FALSE	FALSE		
Addditional Product Identifier Code	AdditionalTradeItemIdentifi cationTypeCode	Version or Model Number	n/a	FDA_NDC_10	FDA_NDC_10	FDA_NDC_10		
Additional Product Identifier	additionalTradeItemIdentifi cationValue	Version or Model Number	n/a	NDC B	NDC B	NDC B		

Table 3-5.1 EPCIS for DSCSA Attributes with Example Values 2 of 3 - Marked Blister Cards & Unmarked Cells



Best Practice Guide for Sharing Vital Attributes in Healthcare

	GDSN Attribute	GUDID	Packaging Level					
Common Name		Data Element	Unit of Use	Level Below Base Base Unit (Card)	Box / Base Unit	Case		
Manufacture r Name	partyName (mfg name)	n/a	n/a	Pharma Products Inc	Pharma Products Inc	Pharma Products Inc		
Manufacture r GLN	gln (mfg)	n/a	n/a	0614141000029	0614141000029	0614141000029		
Functional Name	functionalName	n/a	n/a	Generic Medication 100MG	Generic Medication 100MG	Generic Medication 100MG		
Quantity of Children	quantityOfChildren	n/a	n/a	n/a	1	1		
Total Quantity of Units Contained	totalQuantityOfNextLowerL evelTradeItem	n/a	n/a	5	3	12		
Consumer Unit Indicator	isTradeItemAConsumerUnit	n/a	n/a	TRUE	TRUE	FALSE		
Invoice Unit Indicator	isTradeItemAnInvoiceUnit	n/a	n/a	FALSE	FALSE	TRUE		
Shipping Unit Indicator	isTradeItemADespatchUnit	n/a	n/a	FALSE	FALSE	TRUE		
Variable Measure Unit Indicator	isTradeItemAVariableUnit	n/a	n/a	FALSE	FALSE	FALSE		
Effective Date	effectiveDateTime	being researched	n/a	2020-01-01T04:00:00Z	2020-01- 01T04:00:00Z	2020-01- 01T04:00:00Z		
End Availability Date/Time	endAvailabilityDateTime	n/a	n/a	9999-12-31T23:59:59Z	9999-12- 31T23:59:59Z	9999-12- 31T23:59:59Z		
Dosage Form Type	dosageFormTypeCodeRefer ence	n/a	n/a	CAPSULE	CAPSULE	CAPSULE		
Ingredient Strength	ingredientStrength	n/a	n/a	100 MG	100 MG	100 MG		
Data Carrier Type Code	DataCarrierTypeCode	n/a	n/a	GS1_DATA_MATRIX	GS1_DATA_MAT RIX	GS1_DATA_MAT RIX		
Serial Number Location Code	SerialNumberLocationCode	Serial Number	n/a	MARKED ON PACKAGING	MARKED ON PACKAGING	MARKED ON PACKAGING		
Has Batch Number	hasBatchNumber	Lot or Batch Number	n/a	TRUE	TRUE	TRUE		
Trade Item Date on Packaging Code	tradeItemDateOnPackaging TypeCode	By Expiration Date	n/a	EXPIRATION_DATE	EXPIRATION_DA TE	EXPIRATION_DA TE		



Common		GUDID Data Element	Packaging Level				
Name	GDSN Attribute		Base Unit of Use	Level Below Base Card	Box / Base Unit	Case	
Product Description	tradeItemDescription	Device Description	Generic Medication 100 mg Tablet 1EA	Generic Medication 100 mg Tablet CG/5 NET QTY 5	Generic Medication 100 mg BX/3 CG/5 NET QTY 15	Generic Medication 100 mg Tablet CA/12 BX/3 CG/5 NET QTY 180	
Product Identifier	globalTradeItemNumber (GTIN)	DI (device identifier)	GTIN F	GTIN G	GTIN H	GTIN I	
Brand Name	brandName	Brand Name	Unbranded	unbranded	unbranded	unbranded	
GPC Code	gpcCategoryCode	n/a	10005845	10005845	10005845	10005845	
Net Content	netContent (& UOM)	Device Count / Quantity per Package	1 EA	5 EA; 1 CG	15 EA; 3 CG	180 EA; 36 CG	
Country of Sale / Target Market	targetMarketCountryCode	n/a	001	001	001	001	
Next Lower Level Package Identifier	tradeltemIdentificationOfNextLowe rLevelTradeItem (GTIN)	n/a	n/a	GTIN F	GTIN G	GTIN H	
Quantity of next lower level package	quantityOfNextLowerLevelTradeIte m	n/a	n/a	5	3	12	
Unit of Use DI	componentIdentification	Unit of Use DI Number	n/a	n/a	n/a	n/a	
Unit Descriptor	TradeItemUnitDescriptorCode	n/a	BASE_UNIT_OR_ EACH	PACK_OR_INNER _PACK	PACK_OR_INNER _PACK	CASE	
Name of Informatio n Provider	partyName	n/a	Pharma Products Inc	Pharma Products Inc	Pharma Products Inc	Pharma Products Inc	
GLN of Informatio n Provider	gln (info provider)	n/a	0614141000029	0614141000029	0614141000029	0614141000029	
Is Trade Item an Orderable Unit?	isTradeItemAnOrderableUnit	n/a	FALSE	FALSE	TRUE	TRUE	
Is Trade Item a Base Unit?	isTradeItemABaseUnit	n/a	TRUE	FALSE	FALSE	FALSE	
Addditional Product Identifier Code	AdditionalTradeItemIdentificationT ypeCode	Version or Model Number	FDA_NDC_10	FDA_NDC_10	FDA_NDC_10	FDA_NDC_10	
Additional Product Identifier	additionalTradeItemIdentificationV alue	Version or Model Number	NDC C	NDC C	NDC C	NDC C	
Manufactur er Name	partyName (mfg name)	n/a	Pharma Products Inc	Pharma Products Inc	Pharma Products Inc	Pharma Products Inc	

Table 3-5.2 EPCIS for DSCSA Attributes with Example Values 3 of 3 - Marked Blister Cards & Marked Cells



Best Practice Guide for Sharing Vital Attributes in Healthcare

	GDSN Attribute	GUDID Data Element	Packaging Level				
Common Name			Base Unit of Use	Level Below Base Card	Box / Base Unit	Case	
Manufactur er GLN	gln (mfg)	n/a	0614141000029	0614141000029	0614141000029	0614141000029	
Functional Name	functionalName	n/a	Generic Medication 100MG	Generic Medication 100MG	Generic Medication 100MG	Generic Medication 100MG	
Quantity of Children	quantityOfChildren	n/a	n/a	1	1	1	
Total Quantity of Units Contained	totalQuantityOfNextLowerLevelTra deltem	n/a	n/a	5	3	12	
Consumer Unit Indicator	isTradeItemAConsumerUnit	n/a	TRUE	TRUE	FALSE	FALSE	
Invoice Unit Indicator	isTradeItemAnInvoiceUnit	n/a	FALSE	FALSE	TRUE	TRUE	
Shipping Unit Indicator	isTradeItemADespatchUnit	n/a	FALSE	FALSE	TRUE	TRUE	
Variable Measure Unit Indicator	isTradeItemAVariableUnit	n/a	FALSE	FALSE	FALSE	FALSE	
Effective Date	effectiveDateTime	being researched	2020-01- 01T04:00:00Z	2020-01- 01T04:00:00Z	2020-01- 01T04:00:00Z	2020-01- 01T04:00:00Z	
End Availability Date/Time	endAvailabilityDateTime	n/a	9999-12- 31T23:59:59Z	9999-12- 31T23:59:59Z	9999-12- 31T23:59:59Z	9999-12- 31T23:59:59Z	
Dosage Form Type	dosageFormTypeCodeReference	n/a	CAPSULE	CAPSULE	CAPSULE	CAPSULE	
Ingredient Strength	ingredientStrength	n/a	100 MG	100 MG	100 MG	100 MG	
Data Carrier Type Code	DataCarrierTypeCode	n/a	GS1_DATA_MAT RIX	GS1_DATA_MAT RIX	GS1_DATA_MAT RIX	GS1_DATA_MAT RIX	
Serial Number Location Code	SerialNumberLocationCode	Serial Number	MARKED_ON_PA CKAGING	MARKED ON PACKAGING	MARKED ON PACKAGING	MARKED ON PACKAGING	
Has Batch Number	hasBatchNumber	Lot or Batch Number	TRUE	TRUE	TRUE	TRUE	
Trade Item Date on Packaging Code	tradeItemDateOnPackagingTypeCo de	By Expiration Date	EXPIRATION_DA TE	EXPIRATION_DA TE	EXPIRATION_DA TE	EXPIRATION_DA TE	



3.4 Attributes for Point of Care Scanning

In addition to the attributes in section 3.1, 3.2, and 3.3, the following attributes have been deemed required by healthcare stakeholders to support point of care scanning in the patient care environment.

3.4.1 Quantity of Inner pack (quantityOfInnerPack)

Note: 'quantityOfInnerPack' and the next attribute, 'quantityOfNextLevelTradeI temWithinInnerPack' were added as vital attributes by the POC workgroup in order to assure that providers would be able to calculate the number of units of use (UoU) in packages below the GDSN base level. Since that time, GS1 has clarified UoU within the <u>GS1</u> <u>Healthcare GTIN Allocation Rules</u> inclusive of a recommendation that medical devices not have more than one level below base. That along with this work group's proposed recommendation that all trade item descriptions include a packaging string along with the net quantity of UoU may obviate the need to use these two attributes unless the trade item is an exception and has more than two levels below base. The workgroup members chose to include the attributes in this best practice guide to support the rare circumstances when a device might include more than one level below the each.

Whote: None of the examples used in this document include values for these attributes.

- 'quantityOfInnerPack' Use this for Unit Quantity if lower-level packaging exists with no GTIN (Indicates the number of non-GTIN assigned inner-packs of next lower-level trade items within the current GTIN level). This attribute should be used only if a product indeed has more than two levels below base. This situation should be avoided by manufacturers as recommended in the <u>GS1</u> <u>Healthcare GTIN Allocation Rules</u> "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"
- If used, 'quantityOfInnerPack' indicates the number of non-GTIN assigned inner-packs of next lower-level trade items within the current package. Along with 'quantityOfNextLevelTradeItemWithinInnerPack' this will allow data consumers to understand the actual number of units of use within the package.

3.4.2 Quantity of Next-Level Trade Item within Inner Pack (quantityOfNextLevelTradeItemWithinInnerPack)

quantityOfNextLevelTradeItemWithinInnerPack' indicates the number of next lower-level trade items contained within the physical non-GTIN assigned each or inner-packs (inner-pack). This attribute should only be used if the item hierarchy has more than one level below base and 'quantityOfInnerPack' has been populated.







Common	GDSN Attribute	GUDID Data Element	Packaging Level				
Name	GDSN Attribute		Unit of Use	Base Unit	Inner Pack	Case	
Product Description	tradeItemDescription	Device Description	Test Strip Blood Glucose 1/EA	Test Strip Blood Glucose VI/25 1EA NET QTY 25	Test Strip Blood Glucose BX/12 VI/25 1/EA NET QTY 300	Test Strip Blood Glucose CA/6 BX/12 VI/25 1/EA NET QTY 1800	
Product Identifier, GTIN	globalTradeItemNumber (GTIN)	DI (device identifier)	GTIN Y	GTIN A	GTIN B	GTIN C	
Brand Name	brandName	Brand Name	n/a	unbranded	unbranded	unbranded	
Global Product Category (GPC) Code	gpcCategoryCode	n/a	n/a	10005844	10005844	10005844	
Net Content & UoM	netContent (& UOM)	Device Count / Quantity per Package	n/a	25EA	300EA	1800EA	
Country of Sale / Target Market	targetMarketCountryCode	n/a	n/a	001	001	001	
Child Trade Item	tradeItemIdentificationOfNextLow erLevelTradeItem (GTIN)	n/a	n/a	n/a	GTIN A	GTIN B	
Count of Each Specific Product	quantityOfNextLowerLevelTradeIte m	n/a	n/a	25	12	6	
Unit of Use DI	componentIdentification	Unit of Use DI Number	n/a	GTIN Y	n/a	n/a	



Common		GUDID Data Element	Packaging I	_evel		
Name	GDSN Attribute		Unit of Use	Base Unit	Inner Pack	Case
Unit Descriptor	TradeItemUnitDescriptorCode	n/a	n/a	BASE_UNIT_OR_ EACH	PACK_OR_INNER _PACK	CASE
Name of Information Provider	partyName	n/a	n/a	Healthcare Products Inc	Healthcare Products Inc	Healthcare Products Inc
GLN of Information Provider	gln (info provider)	n/a	n/a	0614141000005	0614141000005	0614141000005
Orderable Unit Indicator	isTradeItemAnOrderableUnit	n/a	n/a	FALSE	TRUE	TRUE
Base Unit Indicator	isTradeItemABaseUnit	n/a	n/a	TRUE	FALSE	FALSE
Additional Product Identifier Code	AdditionalTradeItemIdentificationT ypeCode	Version or Model Number	n/a	SUPPLIER_ASSI GNED	SUPPLIER_ASSI GNED	SUPPLIER_ASSIGNED
Additional Product Identifier	additionalTradeItemIdentificationV alue	Version or Model Number	n/a	Mfr Catalog #A	Mfr Catalog #A	Mfr Catalog #A
Manufacturer Name	partyName (mfg name)	n/a	n/a	Healthcare Products Inc	Healthcare Products Inc	Healthcare Products Inc
Manufacturer GLN	gln (mfg)	n/a	n/a	0614141000005	0614141000005	0614141000005
Functional Name	functionalName	n/a	n/a	Glucose Test Strip	Glucose Test Strip	Glucose Test Strip
Number of Different Products	quantityOfChildren	n/a	n/a	1	1	1
Total Count of All Products	totalQuantityOfNextLowerLevelTra deltem	n/a	n/a	25	12	6
Consumer Unit Indicator	isTradeItemAConsumerUnit	n/a	n/a	TRUE	FALSE	FALSE
Invoice Unit Indicator	isTradeItemAnInvoiceUnit	n/a	n/a	FALSE	TRUE	TRUE
Shipping Unit Indicator	isTradeItemADespatchUnit	n/a	n/a	FALSE	TRUE	TRUE
Variable Measure Unit Indicator	isTradeItemAVariableUnit	n/a	n/a	FALSE	FALSE	FALSE



Common	GDSN Attribute	GUDID	Packaging Level				
Name		Data Element	Unit of Use	Base Unit	Inner Pack	Case	
Effective Date	effectiveDateTime	n/a	n/a	2020-01- 01T04:00:00Z	2020-01- 01T04:00:00Z	2020-01- 01T04:00:00Z	
End Availability Date/Time	endAvailabilityDateTime	n/a	n/a	n/a	n/a	n/a	
Dosage Form Type	dosageFormTypeCodeReference	n/a	n/a	n/a	n/a	n/a	
Ingredient Strength	ingredientStrength	n/a	n/a	n/a	n/a	n/a	
Data Carrier Type Code	DataCarrierTypeCode	n/a	n/a	GS1_DATA_MAT RIX	GS1_DATA_MAT RIX	GS1_DATA_MATRIX	
Serial Number Location Code	SerialNumberLocationCode	Serial Number	n/a	n/a	n/a	n/a	
Has Batch Number	hasBatchNumber	Lot or Batch Number	n/a	TRUE	TRUE	TRUE	
Trade Item Date on Packaging Code	tradeItemDateOnPackagingTypeC ode	By Expiration Date	n/a	EXPIRATION_DA TE	EXPIRATION_DA TE	EXPIRATION_DATE	
Quantity of Inner Pack	quantityOfInnerPack	n/a	n/a	n/a	n/a	n/a	
Quantity of Next Level Trade Item within Inner Pack	quantityOfNextLevelTradeItemWit hinInnerPack	Quantity per package	n/a	n/a	n/a	n/a	



3.5 Other Attributes Recommended for Healthcare

The following list of attributes represent those deemed to be helpful by at least one healthcare supply chain trading partner in executing basic processes.

For example, package measurements aren't required in order to requisition product from a manufacturer but, for facilities with limited storage space, this information is very useful when making the procurement decision in order to know how much product can be safely stored in the space available.

3.5.1 Depth and UOM (depth & MeasurementUnitCode_GDSN)

The depth or length measurement, with its unit of measure, of the item (such as product, case, pallet) according to the GS1 Package Measurement Rules.

- Use the GDSN attribute 'depth' to represent the depth of the trade item as measured according to the <u>GDSN Package Measurement Rules</u>.
- Within GDSN, 'depth' and the depth UoM are two separate attributes, the former being a value and the latter a code value from GS1 GDSN Code List Document (Mar 2020). Note that this document contains multiple code sets and is updated frequently. Also, UoM is not specifically listed but is shown as 'MeasurementUnitCode_GDSN'.

3.5.2 Height and UOM (height & MeasurementUnitCode_GDSN)

The vertical measurement, with its unit of measure, of the item (such as product, case, pallet) according to the GS1 Package Measurement Rules.

- Use the GDSN attribute 'height' to represent the height of the trade item as measured according to the <u>GDSN Package Measurement Rules</u>.
- Within GDSN, 'height' and the height UoM are two separate attributes the former being a value and the latter a code value from GS1 GDSN Code List Document (Mar 2020). Note that this document contains multiple code sets and is updated frequently. Also, UoM is not specifically listed but is shown as 'MeasurementUnitCode_GDSN'.

3.5.3 Width and UOM (width & MeasurementUnitCode_GDSN)

The horizontal measurement, with its unit of measure, of the item (such as product, case, pallet) according to the GS1 Package Measurement Rules.

- Use the GDSN attribute 'width' to represent the width of the trade item as measured according to the GDSN Package Measurement Rules.
- Within GDSN, 'width' and the width UoM are two separate attributes the former being a value and the latter a code value from GS1 GDSN Code List Document (Mar 2020). Note that this document



contains multiple code sets and is updated frequently. Also, UoM is not specifically listed but is shown as 'MeasurementUnitCode_GDSN'.

3.5.4 Gross Weight and UOM (gross weight & MeasurementUnitCode_GDSN)

The total weight of the product including the weight of all its packaging materials.

- Use the GDSN attribute 'grossWeight' to identify the gross weight of the trade item. The gross weight includes all packaging materials of the trade item. At pallet level, the gross weight includes the weight of the pallet itself.
- Within GDSN, 'grossWeight' and the gross weight width UoM are two separate attributes the former being a value and the latter a code value from GS1 GDSN Code List Document (Mar 2020). Note that this document contains multiple code sets and is updated frequently. Also, UoM is not specifically listed but is shown as 'MeasurementUnitCode_GDSN'.

3.5.5 Additional Classification Agency Name (additionalTradeItemClassificationSystemCode)

A code value from 'AdditionalTradeltemClassificationCodeListCode' on the GS1 GDSN Code List Document used to declare the type of the additional product classification that allows a buyer to know which classification system is used.

- For Healthcare, it is recommended to use UNSPSC, or 5.
- Note that the Code List document contains multiple code sets and is updated frequently.

3.5.6 Additional Classification Category Code (additionalTradeltemClassificationCodeValue)

The actual code value for the classification system identified by additionalTradeItemClassificationCodeValue.

- For 'additionalClassificationCategoryCode' use the actual eight-digit code for the trade item from the UNSPSC code set, including at a minimum the segment, family, and class portions with the commodity portion also preferred.
- It is recommended that data publishers also populate and publish 'additionalClassificationCategoryCodeVersion' identifying the particular release of UNSPSC from which the classification code originates.

3.5.7 Packaging Type Code (packagingTypeCode)

The code for the type of package or container of the product; The dominant means used to transport, store, handle, or display the trade item as defined by the data source. This packaging is not used to describe any manufacturing process.

The use of this attribute has been recommended for both OTC/P2P and for point of care data capture. 'packageTypeCode' is a code from the US <u>GDSN Code List "PackageTypeCode_GDSN"</u> representing



the dominant means used to transport, store, handle, or display the trade item as defined by the data source.

3.5.8 Publication Date (publicationDateTime)

The attribute 'publicationDateTime, is recommended for DSCSA for EPCIS. This is the date on which all static data associated with the trade item becomes available for viewing and synchronization.

Data publishers should consult with their data pool regarding format.

3.5.9 Established Name (regulatedProductName)

The prescribed, regulated, or generic product name provided by the seller in adherence with laws, regulations, or administrative provisions applicable in the country. Not all products have a regulated name.

For pharmaceuticals, use the GS1 attribute 'regulatedProductName' representing the prescribed, regulated, or generic product name or denomination that describes the true nature of the item and is sufficiently precise to distinguish it from other products according to country specific regulation. In the US, use the designated FDA Official name, the Compendial name, the USAN Council name, or the common or usual name (section 502(e)(3) of the Act and 21 CFR 299.4). Ordinarily, the established name of a drug will be the compendial name. However, FDA may designate an established name in cases where a monograph does not exist.

3.5.10 Start Availability Date Time (startAvailabilityDateTime)

The date/time when the product can first be sold to or ordered by the consumer.

- Recommended for pharmaceutical items: use the attribute 'startAvailabilityDateTime' representing the date and time (CCYY-MM-DDTHH:MM:SS) from which the trade item becomes available from the supplier, including seasonal or temporary trade item and services.
- Data publishers should consult with their data pool regarding format.

3.5.11 Trade Item Status (GDSN Mandatory; a 'command' to be added by Data Pool)

In GDSN, this is not a true attribute but a 'command' typically added by the Data Source's Data Pool. In cases where it is not, the data source must populate this command field. Trade Item Status indicates if the trade item has been added for the first time (ADD), deleted (DELETE), corrected (CORRECT), or replaced (CHANGE_BY_REFRESH) by the information provider.

- GUDID has specific rules about how and when items and attributes are to be added, changed, or deleted.
- In general, the data provider should communicate the record status utilizing the methodology associated with the data transmission or synchronization methodology employed.



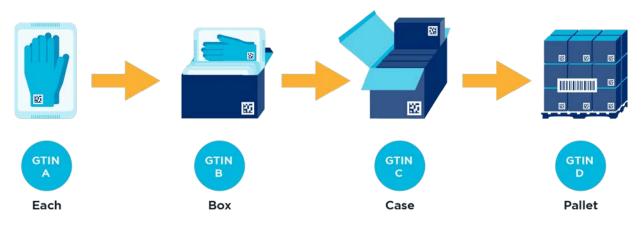


Figure 3-5 Healthcare Recommended Attributes Example

 Table 3-7
 Healthcare Recommended Attributes with Example Values

Common		GUDID Data	Packaging Level				
Name	GDSN Attribute	Element	Pair	Вох	Case	Pallet	
Product Description	tradeItemDescription	Device Description	Glove Surgical Sterile Latex Powder Free Natural Medium, 1/PR NET QTY 1	Glove Surgical Sterile Latex Powder Free Natural Medium, BX/50 1/PR NET QTY 50	Glove Surgical Sterile Latex Powder Free Natural Medium, CS/6 BX/50 1/PR NET QTY 300	Glove Surgical Sterile Latex Powder Free Natural Medium, PL/20 CS/6 BX/50 1/PR NET QTY 6000	
Product Identifier, GTIN	globalTradeItemNumber (GTIN)	DI (device identifier)	GTIN A	GTIN B	GTIN C	GTIN D	
Brand Name	brandName	Brand Name	Healthcare Products	Healthcare Products	Healthcare Products	Healthcare Products	
Global Product Category (GPC) Code	gpcCategoryCode	n/a	10005844	10005844	10005844	10005844	
Net Content & UoM	netContent (& UOM)	Device Count / Quantity per Package	1 PR	50 PR	300 PR	6000 PR	
Country of Sale / Target Market	targetMarketCountryCode	n/a	840	840	840	840	
Child Trade Item	tradeItemIdentificationOfNextLowerL evelTradeItem (GTIN)	n/a	n/a	GTIN A	GTIN B	GTIN C	
Count of Each Specific Product	quantityOfNextLowerLevelTradeItem	n/a	n/a	50	6	20	



Common		GUDID Data	Packaging Level					
Name	GDSN Attribute	Element	Pair	Вох	Case	Pallet		
Unit of Use DI	componentIdentification	Unit of Use DI Number	1 RH Glove Surgical Sterile Latex Powder Free Natural Medium 1 LH Glove Surgical Sterile Latex Powder Free Natural Medium	n/a	n/a	n/a		
Unit Descriptor	TradeItemUnitDescriptorCode	n/a	BASE_UNIT_OR _EACH	PACK_OR_INNER _PACK	CASE	PALLET		
Name of Information Provider	partyName	n/a	Healthcare Products Inc	Healthcare Products Inc	Healthcare Products Inc	Healthcare Products Inc		
GLN of Information Provider	gln (info provider)	n/a	061414100000 5	0614141000005	061414100000 5	061414100000 5		
Orderable Unit Indicator	isTradeItemAnOrderableUnit	n/a	FALSE	FALSE	TRUE	TRUE		
Base Unit Indicator	isTradeItemABaseUnit	n/a	TRUE	FALSE	FALSE	FALSE		
Additional Product Identifier Code	AdditionalTradeItemIdentificationTyp eCode	Version or Model Number	SUPPLIER_ASSI GNED	SUPPLIER_ASSI GNED	SUPPLIER_ASS IGNED	SUPPLIER_ASS IGNED		
Additional Product Identifier	additionalTradeItemIdentificationVal ue	Version or Model Number	SGLNLM9PR	SGLNLM9BX	SGLNLM9CS	SGLNLM9PL		
Manufactur er Name	partyName (mfg name)	n/a	Healthcare Products Inc	Healthcare Products Inc	Healthcare Products Inc	Healthcare Products Inc		
Manufactur er GLN	gln (mfg)	n/a	061414100000 5	0614141000005	061414100000 5	061414100000 5		
Functional Name	functionalName	n/a	Surgical Gloves	Surgical Gloves	Surgical Gloves	Surgical Gloves		
Number of Different Products	quantityOfChildren	n/a	n/a	1	1	1		
Total Count of All Products	totalQuantityOfNextLowerLevelTrade Item	n/a	n/a	50	6	20		
Consumer Unit Indicator	isTradeItemAConsumerUnit	n/a	TRUE	FALSE	FALSE	FALSE		
Invoice Unit Indicator	isTradeItemAnInvoiceUnit	n/a	FALSE	TRUE	TRUE	TRUE		



Common		GUDID Data	Packaging Level					
Name	GDSN Attribute	Element	Pair	Вох	Case	Pallet		
Shipping Unit Indicator	isTradeItemADespatchUnit	n/a	FALSE	TRUE	TRUE	TRUE		
Variable Measure Unit Indicator	isTradeItemAVariableUnit	n/a	FALSE	FALSE	FALSE	FALSE		
Effective Date	effectiveDateTime	being researched	2021-01- 01T04:00:00Z	2021-01- 01T04:00:00Z	2021-01- 01T04:00:00Z	2021-01- 01T04:00:00Z		
End Availability Date/Time	endAvailabilityDateTime	n/a	n/a	n/a	n/a	n/a		
Dosage Form Type	dosageFormTypeCodeReference	n/a	n/a	n/a	n/a	n/a		
Ingredient Strength	ingredientStrength	n/a	n/a	n/a	n/a	n/a		
Data Carrier Type Code	DataCarrierTypeCode	n/a	GS1_DATABAR	GS1_DATABAR	GS1_DATABAR	GS1_DATABAR		
Serial Number Location Code	SerialNumberLocationCode	Serial Number	NOT_MARKED	NOT_MARKED	NOT_MARKED	NOT_MARKED		
Has Batch Number	hasBatchNumber	Lot or Batch Number	TRUE	TRUE	TRUE	TRUE		
Trade Item Date on Packaging Code	tradeItemDateOnPackagingTypeCod e	By Expiration Date	EXPIRATION_D ATE	EXPIRATION_DA TE	EXPIRATION_D ATE	EXPIRATION_D ATE		
Quantity of Inner Pack	quantityOfInnerPack	n/a	n/a	n/a	n/a	n/a		
Quantity of Next Level Trade Item within Inner Pack	quantityOfNextLevelTradeItemWithin InnerPack	Quantity per package	n/a	n/a	n/a	n/a		
Depth & UOM	depth & MeasurementUnitCode_GDSN	n/a	4 INH	8.5 INH	18 INH	48 INH		
Height & UOM	height & MeasurementUnitCode_GDSN	n/a	0.4 INH	10 INH	10.5 INH	58.5 INH		
Width & UOM	width & MeasurementUnitCode_GDSN	n/a	5.5 INH	6 IMH	19 INH	42 INH		
Gross Weight & UOM	grossWeight & MeasurementUnitCode_GDSN	n/a	1.8 ONZ	3.5 LBR	21 LBR	450 LBR		
Additional Classificatio n Agency	AdditionalTradeItemClassificationSys temCode	FDA Premarket Submission Number (58)	5 (UNSPSC)	5 (UNSPSC)	5 (UNSPSC)	5 (UNSPSC)		



Common		GUDID Data	Packaging Level				
Name	GDSN Attribute	Element	Pair	Вох	Case	Pallet	
Additional Classificatio n Category Code	additionalTradeItemClassificationCod eValue	FDA Premarket Submission Number	42132205	42132205	42132205	42132205	
Additional Classificatio n Version	additionalClassificationCategoryCode Version	n/a	23.0701	23.0701	23.0701	23.0701	
Packaging Type Code	PackageTypeCode_GDSN	Package Type	PLP (peel pack)	BX (Box)	CS (case)	PX (pallet)	
Publication Date	publicationDateTime	n/a	n/a	n/a	n/a	n/a	
Established Name	regulatedProductName	n/a	n/a	n/a	n/a	n/a	
Start Availability Date/Time	startAvailabilityDateTime	n/a	2021-04- 01T04:00:00Z	2021-04- 01T04:00:00Z	2021-04- 01T04:00:00Z	2021-04- 01T04:00:00Z	
Trade Item Status	a 'command' to be added by Data Pool	n/a	ADD	ADD	ADD	ADD	



3.6 Other Attributes Required for GUDID

The following list of attributes, in addition to several in the preceding sections, are also required data elements for medical devices being listed in the U.S. FDA GUDID. For details on these attributes and how to provide this information, please reference the U.S. FDA Guidance document: <u>https://www.fda.gov/medical-devices/global-unique-device-identification-database-guid/guid-guidance</u>

- Issuing Agency
- FDA GMDN PT Code
- Latex Content
- For Single Use Y/N
- Record Publish Date
- Labeler DUNs Number
- Serial # Y/N
- Expiration Date Y/N
- Donation ID Y/N
- MRI Safety
- Device packaged as sterile Y/N
- Device requires sterilization prior to use Y/N



4 Additional Attribution Examples

Figure 4-1 Flow Tubes: one per box, 5 boxes per Inner Pack, 7 Inner Packs per case

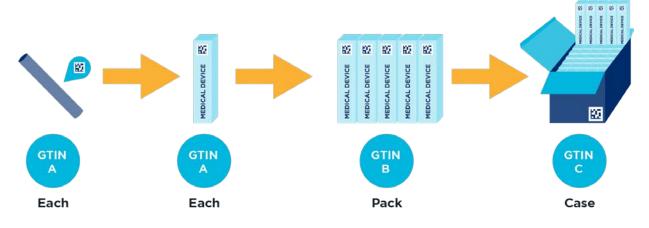


 Table 4-1
 Flow Tubes: one per box, 5 boxes per Inner Pack, 7 Inner Packs per case

			Packaging	g Level		
Common Name	GDSN Attribute	GUDID Data Element	Unit of Use	Base Unit	Inner Pack	Case
Product Description	tradeItemDescription	Device Description	n/a	Flow tube disposable non- sterile 1EA	Flow tubePK/5 1EA NET QTY 5	Flow tube CA/7 PK/5 1EA NET QTY 35
Product Identifier, GTIN	globalTradeItemNumber (GTIN)	DI (device identifier)	n/a	GTIN A	GTIN B	GTIN C
Brand Name	brandName	Brand Name	n/a	unbranded	unbranded	unbranded
Global Product Category (GPC) Code	gpcCategoryCode	n/a	n/a	10005844	10005844	10005844
Net Content & UoM	netContent (& UOM)	Device Count / Quantity per Package	n/a	1EA	5EA	35EA
Country of Sale / Target Market	targetMarketCountryCode	n/a	n/a	001	001	001
Child Trade Item	tradeItemIdentificationOfNextLowe rLeveITradeItem (GTIN)	n/a	n/a	n/a	GTIN A	GTIN B
Count of Each Specific Product	quantityOfNextLowerLevelTradeIte m	n/a	n/a	n/a	5	7
Unit of Use DI	componentIdentification	Unit of Use DI Number	n/a	n/a	n/a	n/a
Unit Descriptor	TradeItemUnitDescriptorCode	n/a	n/a	BASE_UNIT_OR_E ACH	PACK_OR_INNERP ACK	CASE
Name of Information Provider	partyName	n/a	n/a	Healthcare Products Inc	Healthcare Products Inc	Healthcare Products Inc



			Packaging	g Level		
Common Name	GDSN Attribute	GUDID Data Element	Unit of Use	Base Unit	Inner Pack	Case
GLN of Information Provider	gln (info provider)	n/a	n/a	0614141000005	0614141000005	0614141000005
Orderable Unit Indicator	isTradeItemAnOrderableUnit	n/a	n/a	FALSE	FALSE	TRUE
Base Unit Indicator	isTradeItemABaseUnit	n/a	n/a	TRUE	FALSE	FALSE
Additional Product Identifier Code	AdditionalTradeItemIdentificationT ypeCode	Version or Model Number	n/a	SUPPLIER_ASSIG NED	SUPPLIER_ASSIG NED	SUPPLIER_ASSIG NED
Additional Product Identifier	additionalTradeItemIdentificationV alue	Version or Model Number	n/a	FT432101	FT432102	FT432103
Manufacturer Name	partyName (mfg name)	n/a	n/a	Healthcare Products Inc	Healthcare Products Inc	Healthcare Products Inc
Manufacturer GLN	gln (mfg)	n/a	n/a	0614141000005	0614141000005	0614141000005
Functional Name	functionalName	n/a	n/a	Flow Tube	Flow Tube	Flow Tube
Number of Different Products	quantityOfChildren	n/a	n/a	1	1	1
Total Count of All Products	totalQuantityOfNextLowerLevelTra deItem	n/a	n/a	n/a	5	7
Consumer Unit Indicator	isTradeItemAConsumerUnit	n/a	n/a	TRUE	TRUE	FALSE
Invoice Unit Indicator	isTradeItemAnInvoiceUnit	n/a	n/a	FALSE	FALSE	TRUE
Shipping Unit Indicator	isTradeItemADespatchUnit	n/a	n/a	FALSE	FALSE	TRUE
Variable Measure Unit Indicator	isTradeItemAVariableUnit	n/a	n/a	FALSE	FALSE	FALSE
Effective Date	effectiveDateTime	being researched	n/a	2020-01- 01T04:00:00Z	2020-01- 01T04:00:00Z	2020-01- 01T04:00:00Z
End Availability Date/Time	endAvailabilityDateTime	n/a	n/a	n/a	n/a	n/a
Dosage Form Type	dosageFormTypeCodeReference	n/a	n/a	n/a	n/a	n/a
Ingredient Strength	ingredientStrength	n/a	n/a	n/a	n/a	n/a
Data Carrier Type Code	DataCarrierTypeCode	n/a	n/a	GS1_DATA_MATRI X	GS1_DATA_MATRI X	GS1_DATA_MATR IX
Serial Number Location Code	SerialNumberLocationCode	Serial Number	n/a	n/a	n/a	n/a
Has Batch Number	hasBatchNumber	Lot or Batch Number	n/a	n/a	n/a	n/a
Trade Item Date on Packaging Code	tradeItemDateOnPackagingTypeCo de	By Expiration Date	n/a	n/a	n/a	n/a
Quantity of Inner Pack	quantityOfInnerPack	n/a	n/a	n/a	n/a	n/a
Quantity of Next Level Trade Item within Inner Pack	quantityOfNextLevelTradeItemWith inInnerPack	Quantity per package	n/a	n/a	n/a	n/a



			Packaging Level				
Common Name	GDSN Attribute	GUDID Data Element	Unit of Use	Base Unit	Inner Pack	Case	
Depth & UOM	depth & MeasurementUnitCode_GDSN	n/a	n/a	35 MMT	45 MMT	350 MMT	
Height & UOM	height & MeasurementUnitCode_GDSN	n/a	n/a	120 MMT	135 MMT	150 MMT	
Width & UOM	width & MeasurementUnitCode_GDSN	n/a	n/a	35 MMT	185 MMT	200 MMT	
Gross Weight & UOM	grossWeight & MeasurementUnitCode_GDSN	n/a	n/a	36 GRM	190 GRM	1.4 KGM	
Additional Classification Agency	AdditionalTradeItemClassificationC odeListCode		n/a	5 (UNSPSC)	5 (UNSPSC)	5 (UNSPSC)	
Additional Classification Category Code	additionalClassificationCategoryCo de		n/a	42271640	42271640	42271640	
Additional Classification Version	additionalClassificationCategoryCo deVersion	n/a	n/a	22.0601	22.0601	22.0601	
Packaging Type Code	PackageTypeCode_GDSN	Package Type	n/a	NE (Not Packed)	BG (Bag)	CS (case)	
Publication Date	publicationDateTime	n/a	n/a	n/a	n/a	n/a	
Established Name	regulatedProductName	n/a	n/a	n/a	n/a	n/a	
Start Availability Date/Time	startAvailabilityDateTime	n/a	n/a	n/a	n/a	n/a	
Trade Item Status	a 'command' to be added by Data Pool	n/a	n/a	ADD	ADD	ADD	



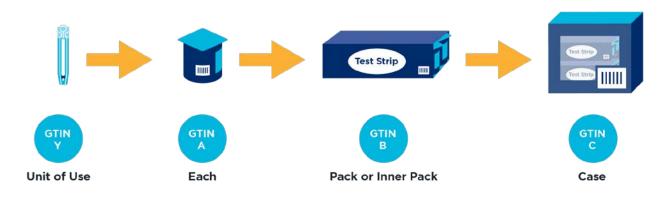


Figure 4-2 Blood Glucose Strips: Vial of 25 ea., Box of 12 vials, case of 6 boxes

Table 4-2	Blood Glucose Strips:	Vial of 25 ea.,	Box of 12 vials,	case of 6 boxes
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		GUDID	Packaging Level				
Common Name	GDSN Attribute	Data Element	Unit of Use	Base Unit	Inner Pack	Case	
Product Description	tradeItemDescription	Device Descripti on	Test Strip Blood Glucose 1/EA	Test Strip Blood Glucose VI/25 1EA NET QTY 25	Test Strip Blood Glucose BX/12 VI/25 1/EA NET QTY 300	Test Strip Blood Glucose CA/6 BX/12 VI/25 1/EA NET QTY 1800	
Product Identifier, GTIN	globalTradeItemNumber (GTIN)	DI (device identifier)	GTIN Y	GTIN A	GTIN B	GTIN C	
Brand Name	brandName	Brand Name		unbranded	unbranded	unbranded	
Global Product Category (GPC) Code	gpcCategoryCode	n/a	100058 44	10005844	10005844	10005844	
Net Content & UoM	netContent (& UOM)	Device Count / Quantity per Package	n/a	25EA	300EA	1800EA	
Country of Sale / Target Market	targetMarketCountryCode	n/a	n/a	001	001	001	
Child Trade Item	tradeItemIdentificationOfNextLowerLeveIT radeItem (GTIN)	n/a	n/a	n/a	GTIN A	GTIN B	
Count of Each Specific Product	quantityOfNextLowerLevelTradeItem	n/a	n/a	25	12	6	
Unit of Use DI	componentIdentification	Unit of Use DI Number	n/a	GTIN Y	n/a	n/a	
Unit Descriptor	TradeItemUnitDescriptorCode	n/a	n/a	BASE_UNIT_OR_E ACH	PACK_OR_INNER_P ACK	CASE	
Name of Information Provider	partyName	n/a	n/a	Healthcare Products Inc	Healthcare Products Inc	Healthcare Products Inc	
GLN of Information Provider	gln (info provider)	n/a	n/a	0614141000005	0614141000005	0614141000005	



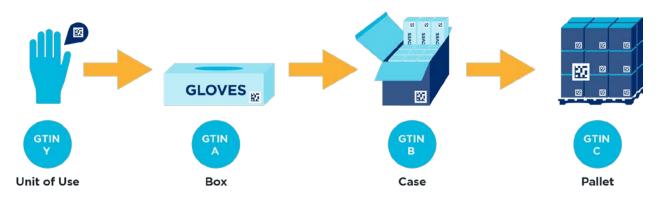
		GUDID	Packagin	ig Level		
Common Name	GDSN Attribute	Data Element	Unit of Use	Base Unit	Inner Pack	Case
Orderable Unit Indicator	isTradeItemAnOrderableUnit	n/a	n/a	FALSE	TRUE	TRUE
Base Unit Indicator	isTradeItemABaseUnit	n/a	n/a	TRUE	FALSE	FALSE
Additional Product Identifier Code	AdditionalTradeltemIdentificationTypeCod e	Version or Model Number	n/a	SUPPLIER_ASSIG NED	SUPPLIER_ASSIGN ED	SUPPLIER_ASSIG NED
Additional Product Identifier	additionalTradeItemIdentificationValue	Version or Model Number	n/a	Mfr Catalog #A	Mfr Catalog #A	Mfr Catalog #A
Manufacturer Name	partyName (mfg name)	n/a	n/a	Healthcare Products Inc	Healthcare Products Inc	Healthcare Products Inc
Manufacturer GLN	gln (mfg)	n/a	n/a	0614141000005	0614141000005	0614141000005
Functional Name	functionalName	n/a	n/a	Glucose Test Strip	Glucose Test Strip	Glucose Test Strip
Number of Different Products	quantityOfChildren	n/a	n/a	1	1	1
Total Count of All Products	totalQuantityOfNextLowerLevelTradeItem	n/a	n/a	25	12	6
Consumer Unit Indicator	isTradeItemAConsumerUnit	n/a	n/a	TRUE	FALSE	FALSE
Invoice Unit Indicator	isTradeItemAnInvoiceUnit	n/a	n/a	FALSE	TRUE	TRUE
Shipping Unit Indicator	isTradeItemADespatchUnit	n/a	n/a	FALSE	TRUE	TRUE
Variable Measure Unit Indicator	isTradeItemAVariableUnit	n/a	n/a	FALSE	FALSE	FALSE
Effective Date	effectiveDateTime	n/a	n/a	2020-01- 01T04:00:00Z	2020-01- 01T04:00:00Z	2020-01- 01T04:00:00Z
End Availability Date/Time	endAvailabilityDateTime	n/a	n/a	n/a	n/a	n/a
Dosage Form Type	dosageFormTypeCodeReference	n/a	n/a	n/a	n/a	n/a
Ingredient Strength	ingredientStrength	n/a	n/a	n/a	n/a	n/a
Data Carrier Type Code	DataCarrierTypeCode	n/a	n/a	GS1_128	GS1_128	GS1_128
Serial Number Location Code	SerialNumberLocationCode	Serial Number	n/a	n/a	n/a	n/a
Has Batch Number	hasBatchNumber	Lot or Batch Number	n/a	TRUE	TRUE	TRUE
Trade Item Date on Packaging Code	tradeItemDateOnPackagingTypeCode	By Expiratio n Date	n/a	EXPIRATION_DAT E	EXPIRATION_DATE	EXPIRATION_DAT E
Quantity of Inner Pack	quantityOfInnerPack	n/a	n/a	n/a	n/a	n/a
Quantity of Next Level Trade Item within Inner Pack	quantityOfNextLevelTradeItemWithinInner Pack	Quantity per package	n/a	n/a	n/a	n/a
Depth & UOM	depth & MeasurementUnitCode_GDSN	n/a	n/a	1 INH	3.5 INH	22 INH



		GUDID	Packagin	g Level		
Common Name	GDSN Attribute	Data Element	Unit of Use	Base Unit	Inner Pack	Case
Height & UOM	height & MeasurementUnitCode_GDSN	n/a	n/a	3 INH	3.5 INH	5.5 INH
Width & UOM	width & MeasurementUnitCode_GDSN	n/a	n/a	1 INH	4.5 INH	4.5 INH
Gross Weight & UOM	grossWeight & MeasurementUnitCode_GDSN	n/a	n/a	0.75 ONZ	9.5 ONZ	60 ONZ
Additional Classification Agency	AdditionalTradeItemClassificationCodeList Code		n/a	5 (UNSPSC)	5 (UNSPSC)	5 (UNSPSC)
Additional Classification Category Code	additionalClassificationCategoryCode		n/a	41116106	41116106	41116106
Additional Classification Version	additionalClassificationCategoryCodeVersio n	n/a	n/a	22.0601	22.0601	22.0601
Packaging Type Code	PackageTypeCode_GDSN	Package Type	n/a	BO (bottle)	BX (box)	CS (case)
Publication Date	publicationDateTime	n/a	n/a	n/a	n/a	n/a
Established Name	regulatedProductName	n/a	n/a	n/a	n/a	n/a
Start Availability Date/Time	startAvailabilityDateTime	n/a	n/a	n/a	n/a	n/a
Trade Item Status	a 'command' to be added by Data Pool	n/a	n/a	ADD	ADD	ADD



Figure 4-3 Exam Gloves: 100 gloves per box, case of 10 boxes, pallet of 70 cases





			Packaging Level			
Common Name	GDSN Attribute	GUDID Data Element	Unit of Use (single glove)	Base Unit	Case	Pallet
Product Description	tradeItemDes cription	Device Description	Gloves, Nitrile, Exam Grade, LG, Disposable BX/100 NET QTY 1	Gloves, Nitrile, Exam Grade, LG, Disposable BX/100 NET QTY 100	Gloves, Nitrile, Exam Grade, LG, Disposable CA/10 BX/100 NET QTY 1000	Gloves, Nitrile, Exam Grade, LG, Disposable PL/70 CA/10 BX/100 NET QTY 70000
Product Identifier, GTIN	globalTradeIt emNumber (GTIN)	DI (device identifier)	GTIN Y	GTIN A	GTIN B	GTIN C
Brand Name	brandName	Brand Name	n/a	unbranded	unbranded	unbranded
Global Product Category (GPC) Code	gpcCategory Code	n/a	n/a	10005844	10005844	10005844
Net Content & UoM	netContent (& UOM)	Device Count / Quantity per Package	n/a	100 EA	1000 EA	70000 EA
Country of Sale / Target Market	targetMarket CountryCode	n/a	n/a	001	001	001
Child Trade Item	tradeItemIde ntificationOfN extLowerLeve ITradeItem (GTIN)	n/a	n/a	n/a	GTIN A	GTIN B
Count of Each Specific Product	quantityOfNe xtLowerLevel TradeItem	n/a	n/a	1	10	70
Unit of Use DI	componentId entification	Unit of Use DI Number	n/a	GTIN Y	n/a	n/a
Unit Descriptor	TradeItemUni tDescriptorCo de	n/a	n/a	BASE_UNIT_OR_EACH	CASE	PALLET
Name of Information Provider	partyName	n/a	n/a	Healthcare Products Inc	Healthcare Products Inc	Healthcare Products Inc
GLN of Information Provider	gln (info provider)	n/a	n/a	0614141000005	0614141000005	0614141000005



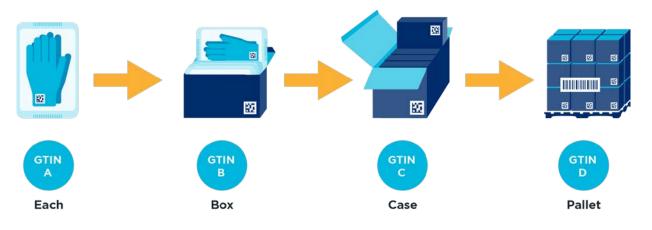
			Packaging Level			
Common Name	GDSN Attribute	GUDID Data Element	Unit of Use (single glove)	Base Unit	Case	Pallet
Orderable Unit Indicator	isTradeItemA nOrderableUn it	n/a	n/a	FALSE	TRUE	TRUE
Base Unit Indicator	isTradeItemA BaseUnit	n/a	n/a	TRUE	FALSE	FALSE
Additional Product Identifier Code	AdditionalTra deltemIdentif icationTypeC ode	Version or Model Number	n/a	SUPPLIER_ASSIGNED	SUPPLIER_ASSIGNED	SUPPLIER_ASSIGNED
Additional Product Identifier	additionalTra deItemIdentif icationValue	Version or Model Number	n/a	Fictitious Catalog# A	Fictitious Catalog# B	Fictitious Catalog# C
Manufacturer Name	partyName (mfg name)	n/a	n/a	Healthcare Products Inc	Healthcare Products Inc	Healthcare Products Inc
Manufacturer GLN	gln (mfg)	n/a	n/a	0614141000005	0614141000005	0614141000005
Functional Name	functionalNa me	n/a	n/a	Exam Glove	Exam Glove	Exam Glove
Number of Different Products	quantityOfChi Idren	n/a	n/a	1	1	1
Total Count of All Products	totalQuantity OfNextLower LevelTradeIte m	n/a	n/a	1	10	70
Consumer Unit Indicator	isTradeItemA ConsumerUni t	n/a	n/a	TRUE	FALSE	FALSE
Invoice Unit Indicator	isTradeItemA nInvoiceUnit	n/a	n/a	FALSE	TRUE	TRUE
Shipping Unit Indicator	isTradeItemA DespatchUnit	n/a	n/a	FALSE	TRUE	TRUE
Variable Measure Unit Indicator	isTradeItemA VariableUnit	n/a	n/a	FALSE	FALSE	FALSE
Effective Date	effectiveDate Time	being researched	n/a	2020-01- 01T04:00:00Z	2020-01- 01T04:00:00Z	2020-01-01T04:00:00Z
End Availability Date/Time	endAvailabilit yDateTime	n/a	n/a	n/a	n/a	n/a
Dosage Form Type	dosageFormT ypeCodeRefe rence	n/a	n/a	n/a	n/a	n/a
Ingredient Strength	ingredientStr ength	n/a	n/a	n/a	n/a	n/a
Data Carrier Type Code	DataCarrierT ypeCode	n/a	n/a	GS1_DATA_MATRIX	GS1_DATA_MATRIX	GS1_DATA_MATRIX
Serial Number Location Code	SerialNumber LocationCode	Serial Number	n/a	NOT_MARKED	NOT_MARKED	NOT_MARKED
Has Batch Number	hasBatchNum ber	Lot or Batch Number	n/a	TRUE	TRUE	TRUE
Trade Item Date on Packaging Code	tradeltemDat eOnPackagin gTypeCode	By Expiration Date	n/a	EXPIRATION_DATE	EXPIRATION_DATE	EXPIRATION_DATE
Quantity of Inner Pack	quantityOfInn erPack	n/a	n/a	n/a	n/a	n/a
Quantity of Next Level Trade Item	quantityOfNe xtLevelTradel temWithinInn erPack	Quantity per package	n/a	n/a	n/a	n/a



			Packaging Level			
Common Name	GDSN Attribute	GUDID Data Element	Unit of Use (single glove)	Base Unit	Case	Pallet
within Inner Pack						
Depth & UOM	depth & Measurement UnitCode_GD SN	n/a	n/a	240 MMT	324 MMT	1220 MMT
Height & UOM	height & Measurement UnitCode_GD SN	n/a	n/a	60 MMT	232 MMT	1777 MMT
Width & UOM	width & Measurement UnitCode_GD SN	n/a	n/a	120 MMT	230 MMT	1016 MMT
Gross Weight & UOM	grossWeight & Measurement UnitCode_GD SN	n/a	n/a	500 GRM	5.100 KGM	375 KGM
Additional Classification Agency	AdditionalTra deItemClassif icationSyste mCode		n/a	5 (UNSPSC)	5 (UNSPSC)	5 (UNSPSC)
Additional Classification Category Code	additionalTra deItemClassif icationCodeV alue		n/a	42132203	42132203	42132203
Additional Classification Version	additionalCla ssificationCat egoryCodeVe rsion	n/a	n/a	23.0701	23.0701	23.0701
Packaging Type Code	PackageType Code_GDSN	Package Type	n/a	BX (Box)	CS (case)	PX (pallet)
Publication Date	publicationDa teTime	n/a	n/a	n/a	n/a	n/a
Established Name	regulatedPro ductName	n/a	n/a	n/a	n/a	n/a
Start Availability Date/Time	startAvailabili tyDateTime	n/a	n/a	2020-01- 01T04:00:00Z	2020-01- 01T04:00:00Z	2020-01-01T04:00:00Z
Trade Item Status	a 'command' to be added by Data Pool	n/a	n/a	ADD	ADD	ADD



Figure 4-4 Surgical gloves: one sterile pair, box of 10 pair, case of 10 boxes, pallet of 20 cases





Common		GUDID Data	Packaging Level			
Name	GDSN Attribute	Element	Pair	Вох	Case	Pallet
Product Description	tradeItemDescription	Device Description	Glove Surgical Sterile Latex Powder Free Natural Medium, 1/PR NET QTY 1	Glove Surgical Sterile Latex Powder Free Natural Medium, BX/50 1/PR NET QTY 50	Glove Surgical Sterile Latex Powder Free Natural Medium, CS/6 BX/50 1/PR NET QTY 300	Glove Surgical Sterile Latex Powder Free Natural Medium, PL/20 CS/6 BX/50 1/PR NET QTY 6000
Product Identifier, GTIN	globalTradeItemNumber (GTIN)	DI (device identifier)	GTIN A	GTIN B	GTIN C	GTIN D
Brand Name	brandName	Brand Name	Healthcare Products	Healthcare Products	Healthcare Products	Healthcare Products
Global Product Category (GPC) Code	gpcCategoryCode	n/a	10005844	10005844	10005844	10005844
Net Content & UoM	netContent (& UOM)	Device Count / Quantity per Package	1 PR	50 PR	300 PR	6000 PR
Country of Sale / Target Market	targetMarketCountryCode	n/a	840	840	840	840
Child Trade Item	tradeItemIdentificationOfNextLowe rLevelTradeItem (GTIN)	n/a	n/a	GTIN A	GTIN B	GTIN C
Count of Each Specific Product	quantityOfNextLowerLevelTradeIte m	n/a	n/a	50	6	20
Unit of Use	componentIdentification	Unit of Use DI	1 RH Glove Surgical Sterile Latex Powder Free Natural Medium	n/a	n/a	n/a
DI		Number	1 LH Glove Surgical Sterile Latex Powder Free Natural Medium	in d	10.0	17.4
Unit Descriptor	TradeItemUnitDescriptorCode	n/a	BASE_UNIT_OR_E ACH	PACK_OR_INNE R_PACK	CASE	PALLET



Common		GUDID Data	Packaging Level			
Name	GDSN Attribute	Element	Pair	Вох	Case	Pallet
Name of Information Provider	partyName	n/a	Healthcare Products Inc	Healthcare Products Inc	Healthcare Products Inc	Healthcare Products Inc
GLN of Information Provider	gln (info provider)	n/a	0614141000005	0614141000005	061414100000 5	061414100000 5
Orderable Unit Indicator	isTradeItemAnOrderableUnit	n/a	FALSE	FALSE	TRUE	TRUE
Base Unit Indicator	isTradeItemABaseUnit	n/a	TRUE	FALSE	FALSE	FALSE
Additional Product Identifier Code	AdditionalTradeItemIdentificationT ypeCode	Version or Model Number	SUPPLIER_ASSIGN ED	SUPPLIER_ASSI GNED	SUPPLIER_ASS IGNED	SUPPLIER_ASS IGNED
Additional Product Identifier	additionalTradeltemIdentificationV alue	Version or Model Number	SGLNLM9PR	SGLNLM9BX	SGLNLM9CS	SGLNLM9PL
Manufacture r Name	partyName (mfg name)	n/a	Healthcare Products Inc	Healthcare Products Inc	Healthcare Products Inc	Healthcare Products Inc
Manufacture r GLN	gln (mfg)	n/a	0614141000005	0614141000005	061414100000 5	061414100000 5
Functional Name	functionalName	n/a	Surgical Gloves	Surgical Gloves	Surgical Gloves	Surgical Gloves
Number of Different Products	quantityOfChildren	n/a	n/a	1	1	1
Total Count of All Products	totalQuantityOfNextLowerLevelTra deltem	n/a	n/a	50	6	20
Consumer Unit Indicator	isTradeItemAConsumerUnit	n/a	TRUE	FALSE	FALSE	FALSE
Invoice Unit Indicator	isTradeItemAnInvoiceUnit	n/a	FALSE	TRUE	TRUE	TRUE
Shipping Unit Indicator	isTradeItemADespatchUnit	n/a	FALSE	TRUE	TRUE	TRUE
Variable Measure Unit Indicator	isTradeItemAVariableUnit	n/a	FALSE	FALSE	FALSE	FALSE
Effective Date	effectiveDateTime	being researched	2021-01- 01T04:00:00Z	2021-01- 01T04:00:00Z	2021-01- 01T04:00:00Z	2021-01- 01T04:00:00Z
End Availability Date/Time	endAvailabilityDateTime	n/a				
Dosage Form Type	dosageFormTypeCodeReference	n/a	n/a	n/a	n/a	n/a
Ingredient Strength	ingredientStrength	n/a	n/a	n/a	n/a	n/a
Data Carrier Type Code	DataCarrierTypeCode	n/a	GS1_DATA_MATRI X	GS1_DATA_MAT RIX	GS1_DATA_MA TRIX	GS1_DATA_MA TRIX
Serial Number Location Code	SerialNumberLocationCode	Serial Number	NOT_MARKED	NOT_MARKED	NOT_MARKED	NOT_MARKED
Has Batch Number	hasBatchNumber	Lot or Batch Number	TRUE	TRUE	TRUE	TRUE
Trade Item Date on Packaging Code	tradeItemDateOnPackagingTypeCo de	By Expiration Date	EXPIRATION_DAT E	EXPIRATION_DA TE	EXPIRATION_D ATE	EXPIRATION_D ATE
Quantity of Inner Pack	quantityOfInnerPack	n/a	n/a	n/a	n/a	n/a



Common		GUDID Data	Packaging Level			
Name	GDSN Attribute	Element	Pair	Вох	Case	Pallet
Quantity of Next Level Trade Item within Inner Pack	quantityOfNextLevelTradeItemWit hinInnerPack	Quantity per package	n/a	n/a	n/a	n/a
Depth & UOM	depth & MeasurementUnitCode_GDSN	n/a	4 INH	8.5 INH	18 INH	48 INH
Height & UOM	height & MeasurementUnitCode_GDSN	n/a	0.4 INH	10 INH	10.5 INH	58.5 INH
Width & UOM	width & MeasurementUnitCode_GDSN	n/a	5.5 INH	6 IMH	19 INH	42 INH
Gross Weight & UOM	grossWeight & MeasurementUnitCode_GDSN	n/a	1.8 ONZ	3.5 LBR	21 LBR	450 LBR
Additional Classificatio n Agency	AdditionalTradeItemClassificationS ystemCode		5 (UNSPSC)	5 (UNSPSC)	5 (UNSPSC)	5 (UNSPSC)
Additional Classificatio n Category Code	additionalTradeItemClassificationC odeValue		42132205	42132205	42132205	42132205
Additional Classificatio n Version	additionalClassificationCategoryCo deVersion	n/a	23.0701	23.0701	23.0701	23.0701
Packaging Type Code	PackageTypeCode_GDSN	Package Type	PLP (peel pack)	BX (Box)	CS (case)	PX (pallet)
Publication Date	publicationDateTime	n/a	n/a	n/a	n/a	n/a
Established Name	regulatedProductName	n/a	n/a	n/a	n/a	n/a
Start Availability Date/Time	startAvailabilityDateTime	n/a	2021-04- 01T04:00:00Z	2021-04- 01T04:00:00Z	2021-04- 01T04:00:00Z	2021-04- 01T04:00:00Z
Trade Item Status	a 'command' to be added by Data Pool	n/a	ADD	ADD	ADD	ADD



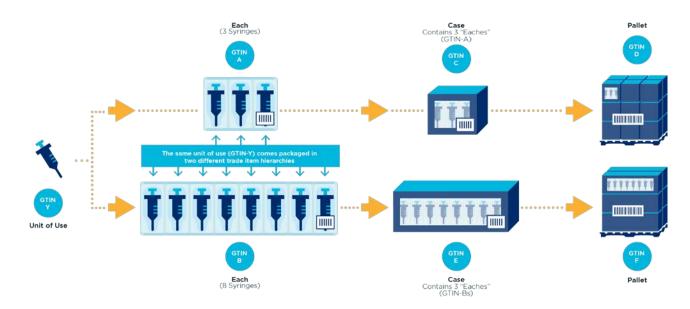


Figure 4-5 Syringes: Two hierarchies for the same device

Table 4-5	Syringes:	First Hierarchy	^r Example – 3	pack, 3 3-pac	ks per box,	18 boxes per pallet
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Common Name	GDSN Attribute	GUDID Data Element	Packaging Level				
Common Name	GDSN Attribute		Unit of Use	Base Unit	Case	Pallet	
Product Description	tradeItemDescripti on	Device Description	Syringe disposable 10ml	Syringe disposable 10ml PK/3	Syringe disposable 10ml BX/3 PK/3 NET QTY 9	Syringe disposable 10ml PL/18 BX/3 PK/3 NET QTY 162	
Product Identifier, GTIN	globalTradeItemN umber (GTIN)	DI (device identifier)	GTIN Y	GTIN A	GTIN C	GTIN D	
Brand Name	brandName	Brand Name	Sterile Stuff	Sterile Stuff	Sterile Stuff	Sterile Stuff	
Global Product Category (GPC) Code	gpcCategoryCode	n/a	10005844	10005844	10005844	10005844	
Net Content & UoM	netContent(& UOM)	Device Count / Quantity per Package	1	3EA	9 EA	162EA	
Country of Sale / Target Market	targetMarketCount ryCode	n/a	001	001	001	001	
Child Trade Item	tradeItemIdentific ationOfNextLower LeveITradeItem (GTIN)	n/a	n/a	GTIN Y	GTIN A	GTIN C	
Count of Each Specific Product	quantityOfNextLo werLevelTradeIte m	n/a	n/a	3	3	18	
Unit of Use DI	componentIdentifi cation	Unit of Use DI Number	n/a	GTIN Y	GTIN Y	GTIN Y	



		GUDID Data Element	Packaging Level			
Common Name	GDSN Attribute		Unit of Use	Base Unit	Case	Pallet
Unit Descriptor	TradeItemUnitDes criptorCode	n/a	n/a	РК	Case	PL
Name of Information Provider	partyName	n/a	Distribution Company A	Distribution Company A	Distribution Company A	Distribution Company A
GLN of Information Provider	gln (info provider)	n/a	0614141000012	0614141000012	0614141000012	0614141000012
Orderable Unit Indicator	isTradeItemAnOrd erableUnit	n/a	N	Y	Y	Y
Base Unit Indicator	isTradeItemABase Unit	n/a	N	Y	N	N
Additional Product Identifier Code	AdditionalTradeIte mIdentificationTyp eCode	Version or Model Number	Supplier_Assigned	Supplier_Assigned	Supplier_Assigned	Supplier_Assigned
Additional Product Identifier	additionalTradelte mldentificationVal ue	Version or Model Number	SYR10ML	SYR10ML	SYR10ML	SYR10ML
Manufacturer Name	partyName (mfg name)	n/a	Healthcare Products Inc	Healthcare Products Inc	Healthcare Products Inc	Healthcare Products Inc
Manufacturer GLN	gln (mfg)	n/a	0614141000005	0614141000005	0614141000005	0614141000005
Functional Name	functionalName	n/a	Syringe	Syringe	Syringe	Syringe
Number of Different Products	quantityOfChildren	n/a	n/a	1	1	1
Total Count of All Products	totalQuantityOfNe xtLowerLevelTrad eItem	n/a	n/a	3	3	6
Consumer Unit Indicator	isTradeItemACons umerUnit	n/a	Y	N	N	N
Invoice Unit Indicator	isTradeItemAnInv oiceUnit	n/a	N	N	Y	N
Shipping Unit Indicator	isTradeItemADesp atchUnit	n/a	N	N	Y	Y
Variable Measure Unit Indicator	isTradeItemAVaria bleUnit	n/a	N	N	N	N
Effective Date	effectiveDateTime	being researched	2020-01- 01T04:00:00Z	2020-01- 01T04:00:00Z	2020-01- 01T04:00:00Z	2020-01- 01T04:00:00Z
End Availability Date/Time	endAvailabilityDat eTime	n/a	n/a	n/a	n/a	n/a
Dosage Form Type	dosageFormTypeC odeReference	n/a	n/a	n/a	n/a	n/a



		GUDID Data	Packaging Level			
Common Name	GDSN Attribute	Element	Unit of Use	Base Unit	Case	Pallet
Ingredient Strength	ingredientStrength	n/a	n/a	n/a	n/a	n/a
Data Carrier Type Code	DataCarrierTypeC ode	n/a	GS1-128	GS1-128	GS1-128	GS1-128
Serial Number Location Code	SerialNumberLoca tionCode	Serial Number	N	Ν	Ν	N
Has Batch Number	hasBatchNumber	Lot or Batch Number	Y	Y	Y	Y
Trade Item Date on Packaging Code	tradeItemDateOnP ackagingTypeCode	By Expiration Date	Y	Y	Y	Y
Quantity of Inner Pack	quantityOfInnerPa ck	n/a	n/a	n/a	n/a	n/a
Quantity of Next Level Trade Item within Inner Pack	quantityOfNextLev elTradeItemWithin InnerPack	Quantity per package	n/a	n/a	n/a	n/a
Depth & UOM	depth & MeasurementUnit Code_GDSN	n/a	n/a	n/a	n/a	n/a
Height & UOM	height & MeasurementUnit Code_GDSN	n/a	n/a	n/a	n/a	n/a
Width & UOM	width & MeasurementUnit Code_GDSN	n/a	n/a	n/a	n/a	n/a
Gross Weight & UOM	grossWeight & MeasurementUnit Code_GDSN	n/a	n/a	n/a	n/a	n/a
Additional Classification Agency	AdditionalTradeIte mClassificationCod eListCode	n/a	5 for UNSPC	5 for UNSPC	5 for UNSPC	5 for UNSPC 58 PMA sub
Additional Classification Category Code	additionalClassific ationCategoryCod e	n/a	n/a	n/a	n/a	n/a
Additional Classification Version	additionalClassific ationCategoryCod eVersion	n/a	n/a	n/a	n/a	n/a
Packaging Type Code	PackageTypeCode _GDSN	Package Type	PLP	PLP	CS	n/a
Publication Date	publicationDateTi me	n/a	n/a	n/a	n/a	n/a
Established Name	regulatedProductN ame	n/a	n/a	n/a	n/a	n/a
Start Availability Date/Time	startAvailabilityDa teTime	n/a	n/a	n/a	n/a	n/a
Trade Item Status	a 'command' to be added by Data Pool	n/a	n/a	n/a	n/a	n/a



Common Name	GDSN Attribute	GUDID Data Element	Packaging Level				
			Unit of Use	Base Unit	Case	Pallet	
Product Description	tradeItemDescription	Device Descripti on	Syringe disposable 10ml	Syringe disposable 10ml PK/8	Syringe disposable 10ml BX/3 PK/8 NET QTY 24	Syringe disposable 10ml PL/6 BX/3 PK/8 NET QTY 144	
Product Identifier, GTIN	globalTradeItemNumber (GTIN)	DI (device identifier)	GTIN Y	GTIN B	GTIN E	GTIN F	
Brand Name	brandName	Brand Name	n/a	Sterile Stuff	Sterile Stuff	Sterile Stuff	
Global Product Category (GPC) Code	gpcCategoryCode	n/a	n/a	10005844	10005844	10005844	
Net Content & UoM	netContent (& UOM)	Device Count / Quantity per Package	n/a	8EA	24EA	144EA	
Country of Sale / Target Market	targetMarketCountryCode	n/a	n/a	001	001	001	
Child Trade Item	tradeItemIdentificationOfNextLowerLevelTra deItem (GTIN)	n/a	n/a	GTIN Y	GTIN B	GTIN E	
Count of Each Specific Product	quantityOfNextLowerLevelTradeItem	n/a	n/a	8	3	6	
Unit of Use DI	componentIdentification	Unit of Use DI Number	n/a	GTIN Y	GTIN Y	GTIN Y	
Unit Descriptor	TradeItemUnitDescriptorCode	n/a	n/a	BASE_UNIT_OR_E ACH	CASE	PALLET	
Name of Information Provider	partyName	n/a	n/a	Distribution Company A	Distribution Company A	Distribution Company A	
GLN of Information Provider	gln (info provider)	n/a	n/a	0614141000012	061414100001 2	061414100001 2	
Orderable Unit Indicator	isTradeItemAnOrderableUnit	n/a	n/a	N	Y	Y	
Base Unit Indicator	isTradeItemABaseUnit	n/a	n/a	Y	N	N	
Additional Product Identifier Code	AdditionalTradeItemIdentificationTypeCode	Version or Model Number	n/a	Supplier_Assigned	Supplier_Assign ed	Supplier_Assign ed	
Additional Product Identifier	additionalTradeItemIdentificationValue	Version or Model Number	n/a	SYR10ML	SYR10ML	SYR10ML	
Manufacturer Name	partyName (mfg name)	n/a	n/a	Healthcare Products Inc	Healthcare Products Inc	Healthcare Products Inc	

Table 4-5.1 Syringes: Second Hierarchy Example - 8 pack, 3 8-packs per box, 6 boxes per pallet



Common	GDSN Attribute	GUDID	Packaging Level				
Name		Data Element	Unit of Use	Base Unit	Case	Pallet	
Manufacturer GLN	gln (mfg)	n/a	n/a	0614141000005	061414100000 5	061414100000 5	
Functional Name	functionalName	n/a	n/a	Syringe	Syringe	Syringe	
Number of Different Products	quantityOfChildren	n/a	n/a	1	1	1	
Total Count of All Products	totalQuantityOfNextLowerLevelTradeItem	n/a	n/a	8	3	6	
Consumer Unit Indicator	isTradeItemAConsumerUnit	n/a	n/a	Ν	N	N	
Invoice Unit Indicator	isTradeItemAnInvoiceUnit	n/a	n/a	N	Y	N	
Shipping Unit Indicator	isTradeItemADespatchUnit	n/a	n/a	Ν	Y	Y	
Variable Measure Unit Indicator	isTradeItemAVariableUnit	n/a	n/a	Ν	Ν	Ν	
Effective Date	effectiveDateTime	being research ed	n/a	2020-01- 01T04:00:00Z	2020-01- 01T04:00:00Z	2020-01- 01T04:00:00Z	
End Availability Date/Time	endAvailabilityDateTime	n/a	n/a	n/a	n/a	n/a	
Dosage Form Type	dosageFormTypeCodeReference	n/a	n/a	n/a	n/a	n/a	
Ingredient Strength	ingredientStrength	n/a	n/a	n/a	n/a	n/a	
Data Carrier Type Code	DataCarrierTypeCode	n/a	n/a	GS1_128	GS1-128	GS1-128	
Serial Number Location Code	SerialNumberLocationCode	Serial Number	n/a	N	N	N	
Has Batch Number	hasBatchNumber	Lot or Batch Number	n/a	Y	Y	Y	
Trade Item Date on Packaging Code	tradeItemDateOnPackagingTypeCode	By Expiratio n Date	n/a	Y	Y	Y	
Quantity of Inner Pack	quantityOfInnerPack	n/a	n/a	n/a	n/a	n/a	
Quantity of Next Level Trade Item within Inner Pack	quantityOfNextLevelTradeItemWithinInnerPa ck	Quantity per package	n/a	n/a	n/a	n/a	
Depth & UOM	depth & MeasurementUnitCode_GDSN	n/a	n/a	n/a	n/a	n/a	



Common		GUDID	Packaging Level				
Name	GDSN Attribute	Data Element	Unit of Use	Base Unit	Case	Pallet	
Height & UOM	height & MeasurementUnitCode_GDSN	n/a	n/a	n/a	n/a	n/a	
Width & UOM	width & MeasurementUnitCode_GDSN	n/a	n/a	n/a	n/a	n/a	
Gross Weight & UOM	grossWeight & MeasurementUnitCode_GDSN	n/a	n/a	n/a	n/a	n/a	
Additional Classification Agency	AdditionalTradeItemClassificationCodeListCo de	n/a	n/a	5 for UNSPC	5 for UNSPC	5 for UNSPC	
Additional Classification Category Code	additionalClassificationCategoryCode	n/a	n/a	n/a	n/a	n/a	
Additional Classification Version	additionalClassificationCategoryCodeVersion	n/a	n/a	n/a	n/a	n/a	
Packaging Type Code	PackageTypeCode_GDSN	Package Type	n/a	PLP	CS	n/a	
Publication Date	publicationDateTime	n/a	n/a	n/a	n/a	n/a	
Established Name	regulatedProductName	n/a	n/a	n/a	n/a	n/a	
Start Availability Date/Time	startAvailabilityDateTime	n/a	n/a	n/a	n/a	n/a	
Trade Item Status	a 'command' to be added by Data Pool	n/a	n/a	n/a	n/a	n/a	



Figure 4-6 First Aid Kit using Components (scissors, tape, bandages): kit, pack of 3 kits, case of 6 packs

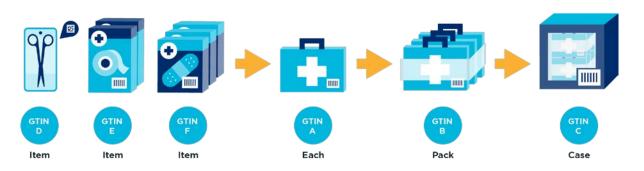


Table 4-6First Aid Kit using Components (scissors, tape, bandages): kit, pack of 3 kits, case of 6
packs

		GUDID Data Element	Packaging Level					
Common Name	GDSN Attribute		Unit of Use	Base Unit	Inner Pack	Case		
Product Descriptio n	tradeItemDescription	Device Descriptio n	n/a	Kit First Aid scissors tape bandages 1/EA	Kit First Aid scissors tape bandages PK/3 1/EA NET QTY 3	Kit First Aid scissors tape bandages CA/6 PK/3 1/EA NET QTY 18		
Product Identifier, GTIN	globalTradeItemNumber (GTIN)	DI (device identifier)	n/a	GTIN A	GTIN B	GTIN C		
Brand Name	brandName	Brand Name	n/a	OUCH Kits	OUCH Kits	OUCH Kits		
Global Product Category (GPC) Code	gpcCategoryCode	n/a	n/a	10005844	10005844	10005844		
Net Content & UoM	netContent (& UOM)	Device Count / Quantity per Package	n/a	1 KT	3 КТ	18 KT		
Country of Sale / Target Market	targetMarketCountryCode	n/a	n/a	001	001	001		
Child Trade Item	tradeltemIdentificationOfNextLowerLevelT radeItem (GTIN)	n/a	n/a	n/a	GTIN A	GTIN B		
Count of Each Specific Product	quantityOfNextLowerLevelTradeItem	n/a	n/a	n/a	1	3		
Unit of Use DI	componentIdentification	Unit of Use DI, Kit or Combinati on Product (refer to FDA guidance)	n/a	1 EA Scissors GTIN D 2 EA Tape GTIN E 3 BX Bandages GTIN F	n/a	n/a		
Unit Descriptor	TradeItemUnitDescriptorCode	n/a	n/a	BASE_UNIT_OR_E ACH	PACK_OR_INNER_P ACK	CASE		



		GUDID Data Element	Packaging Level					
Common Name	GDSN Attribute		Unit of Use	Base Unit	Inner Pack	Case		
Name of Informatio n Provider	partyName	n/a	n/a	Distribution Company A	Distribution Company A	Distribution Company A		
GLN of Informatio n Provider	gln (info provider)	n/a	n/a	0614141000012	0614141000012	0614141000012		
Orderable Unit Indicator	isTradeI temAnOrderableUnit	n/a	n/a	FALSE	TRUE	TRUE		
Base Unit Indicator	isTradeItemABaseUnit	n/a	n/a	TRUE	FALSE	FALSE		
Additional Product Identifier Code	AdditionalTradeItemIdentificationTypeCod e	Version or Model Number	n/a	SUPPLIER_ASSIG NED	SUPPLIER_ASSIGN ED	SUPPLIER_ASSIG NED		
Additional Product Identifier	additionalTradeItemIdentificationValue	Version or Model Number	n/a	FAK9753	FAK9753	FAK9753		
Manufactu rer Name	partyName (mfg name)	n/a	n/a	Healthcare Products Inc	Healthcare Products Inc	Healthcare Products Inc		
Manufactu rer GLN	gln (mfg)	n/a	n/a	0614141000005	0614141000005	0614141000005		
Functional Name	functionalName	n/a	n/a	First Aid Kit	First Aid Kit	First Aid Kit		
Number of Different Products	quantityOfChildren	n/a	n/a	n/a	1	1		
Total Count of All Products	totalQuantityOfNextLowerLevelTradeItem	n/a	n/a	n/a	3	6		
Consumer Unit Indicator	isTradeItemAConsumerUnit	n/a	n/a	TRUE	FALSE	FALSE		
Invoice Unit Indicator	isTradeItemAnInvoiceUnit	n/a	n/a	FALSE	TRUE	TRUE		
Shipping Unit Indicator	isTradeItemADespatchUnit	n/a	n/a	FALSE	TRUE	TRUE		
Variable Measure Unit Indicator	isTradeI temAVariableUnit	n/a	n/a	FALSE	FALSE	FALSE		
Effective Date	effectiveDateTime	being researche d		2020-01- 01T04:00:00Z	2020-01- 01T04:00:00Z	2020-01- 01T04:00:00Z		
End Availability Date/Time	endAvailabilityDateTime	n/a	n/a	n/a	n/a	n/a		
Dosage Form Type	dosageFormTypeCodeReference	n/a	n/a	n/a	n/a	n/a		
Ingredient Strength	ingredientStrength	n/a	n/a	n/a	n/a	n/a		
Data Carrier Type Code	DataCarrierTypeCode	n/a	n/a	GS1-128	GS1-128	GS1-128		
Serial Number Location Code	SerialNumberLocationCode	Serial Number	n/a	n/a	n/a	n/a		



	GDSN Attribute	GUDID Data Element	Packaging Level					
Common Name			Unit of Use	Base Unit	Inner Pack	Case		
Has Batch Number	hasBatchNumber	Lot or Batch Number	n/a	n/a	n/a	n/a		
Trade Item Date on Packaging Code	tradeItemDateOnPackagingTypeCode	By Expiration Date	n/a	n/a	n/a	n/a		
Quantity of Inner Pack	quantityOfInnerPack	n/a	n/a	n/a	n/a	n/a		
Quantity of Next Level Trade Item within Inner Pack	quantityOfNextLevelTradeItemWithinInner Pack	Quantity per package	n/a	n/a	n/a	n/a		
Depth & UOM	depth & MeasurementUnitCode_GDSN	n/a	n/a	5 INH	6 INH	17 INH		
Height & UOM	height & MeasurementUnitCode_GDSN	n/a	n/a	2.5 INH	9 INH	10 INH		
Width & UOM	width & MeasurementUnitCode_GDSN	n/a	n/a	8 INH	9 INH	16 INH		
Gross Weight & UOM	grossWeight & MeasurementUnitCode_GDSN	n/a	n/a	6 ONZ	18.5 ONZ	7.2 LBR		
Additional Classificati on Agency	AdditionalTradeItemClassificationCodeList Code	FDA Premarket Submissio n Number	n/a	5 (UNSPC)	5 (UNSPC)	5 (UNSPC)		
Additional Classificati on Category Code	additionalClassificationCategoryCode	FDA Premarket Submissio n Number	n/a	42192420	42192420	42192420		
Additional Classificati on Version	additionalClassificationCategoryCodeVersio n	n/a	n/a	23	23.0701	23.0701		
Packaging Type Code	PackageTypeCode_GDSN	Package Type	n/a	MPG (Multipack)	BG (Bag)	CS (case)		
Publication Date	publicationDateTime	n/a	n/a	n/a	n/a	n/a		
Establishe d Name	regulatedProductName	n/a	n/a	n/a	n/a	n/a		
Start Availability Date/Time	startAvailabilityDateTime	n/a	n/a	n/a	n/a	n/a		
Trade Item Status	a 'command' to be added by Data Pool	n/a	n/a	ADD	ADD	ADD		



Figure 4-7 First Aid Kit using child GTINs (scissors, tape, bandages): kit, pack of 3 kits, case of 6 packs

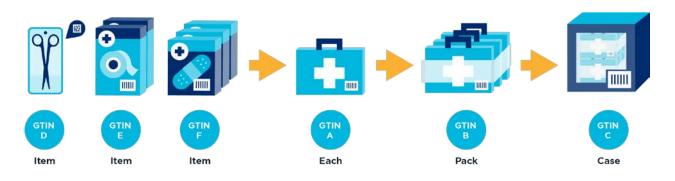


Table 4-7	First Aid Kit using child GTINs (scissors, tape, bandages): kit, pack of 3 kits, case of 6
	packs

	GDSN Attribute	GUDI D Data Element	Packaging Level					
Common Name			Unit of Use	Base Unit	Inner Pack	Case		
Product Description	tradeItemDescription	Device Descriptio n	n/a	Kit First Aid scissors tape bandages 1/EA	Kit First Aid scissors tape bandages PK/3 1/EA NET QTY 3	Kit First Aid scissors tape bandages CA/6 PK/3 1/EA NET QTY 18		
Product Identifier, GTIN	globalTradeItemNumber (GTIN)	DI (device identifier)	n/a	GTIN A	GTIN B	GTIN C		
Brand Name	brandName	Brand Name	n/a	OUCH Kits	OUCH Kits	OUCH Kits		
Global Product Category (GPC) Code	gpcCategoryCode	n/a	n/a	10005844	10005844	10005844		
Net Content & UoM	netContent (& UOM)	Device Count / Quantity per Package	n/a	1 KT	3 КТ	18 KT		
Country of Sale / Target Market	targetMarketCountryCode	n/a	n/a	001	001	001		
Child Trade Item	tradeItemIdentificationOfNextLowerLevel TradeItem (GTIN)	n/a	n/a	n/a	GTIN A	GTIN B		
Count of Each Specific Product	quantityOfNextLowerLevelTradeItem	n/a	n/a	n/a	1	3		
Unit of Use DI	componentIdentification	Unit of Use DI, Kit or Combinati on Product (refer to FDA guidance)	n/a	n/a	n/a	n/a		
Unit Descriptor	TradeItemUnitDescriptorCode	n/a	n/a	BASE_UNIT_OR_E ACH	PACK_OR_INNER_ PACK	CASE		



	GDSN Attribute	GUDID Data Element	Packaging Level					
Common Name			Unit of Use	Bas	e Unit	Inner Pack	Case	
Name of Information Provider	partyName	n/a	n/a		tribution npany A	Distribution Company A	Distribution Company A	
GLN of Information Provider	gln (info provider)	n/a	n/a	061	4141000012	0614141000012	0614141000012	
Orderable Unit Indicator	isTradeItemAnOrderableUnit	n/a	n/a	FALS	SE	TRUE	TRUE	
Base Unit Indicator	isTradeItemABaseUnit	n/a	n/a	TRU	E	FALSE	FALSE	
Additional Product Identifier Code	AdditionalTradeItemIdentificationTypeCo de	Version or Model Number	n/a	SUP NED	PLIER_ASSIG	SUPPLIER_ASSIGN ED	SUPPLIER_ASSIG NED	
Additional Product Identifier	additionalTradeItemIdentificationValue	Version or Model Number	n/a	FAK	9753	FAK9753	FAK9753	
Manufacturer Name	partyName (mfg name)	n/a	n/a		althcare lucts Inc	Healthcare Products Inc	Healthcare Products Inc	
Manufacturer GLN	gln (mfg)	n/a	n/a	061	4141000005	0614141000005	0614141000005	
Functional Name	functionalName	n/a	n/a	First	Aid Kit	First Aid Kit	First Aid Kit	
Number of Different Products	quantityOfChildren	n/a		3	1 EA Scissors GTIN D 2 EA Tape GTIN E 3 BX Bandages	1	1	
Total Count of All Products	totalQuantityOfNextLowerLevelTradeItem	n/a	n/a	6	GTIN F	3	6	
Consumer Unit Indicator	isTradeItemAConsumerUnit	n/a	n/a	TRU	E	FALSE	FALSE	
Invoice Unit Indicator	isTradeItemAnInvoiceUnit	n/a	n/a	FAL	SE	TRUE	TRUE	
Shipping Unit Indicator	isTradeItemADespatchUnit	n/a	n/a	FAL	SE	TRUE	TRUE	
Variable Measure Unit Indicator	isTradeItemAVariableUnit	n/a	n/a	FALS	SE	FALSE	FALSE	
Effective Date	effectiveDateTime	being researche d	n/a		0-01- 04:00:00Z	2020-01- 01T04:00:00Z	2020-01- 01T04:00:00Z	
End Availability Date/Time	endAvailabilityDateTime	n/a	n/a	n/a		n/a	n/a	
Dosage Form Type	dosageFormTypeCodeReference	n/a	n/a	n/a		n/a	n/a	
Ingredient Strength	ingredientStrength	n/a	n/a	n/a		n/a	n/a	
Data Carrier Type Code	DataCarrierTypeCode	n/a	n/a	GS1	-128	GS1-128	GS1-128	
Serial Number Location Code n/a	SerialNumberLocationCode	Serial Number	n/a	n/a		n/a	n/a	
Has Batch Number	hasBatchNumber	Lot or Batch Number	n/a	n/a		n/a	n/a	



	GDSN Attribute	GUDID Data Element	Packaging Level					
Common Name			Unit of Use	Base Unit	Inner Pack	Case		
Trade Item Date on Packaging Code	tradeItemDateOnPackagingTypeCode	By Expiration Date	n/a	n/a	n/a	n/a		
Quantity of Inner Pack	quantityOfInnerPack	n/a	n/a	n/a	n/a	n/a		
Quantity of Next Level Trade Item within Inner Pack	quantityOfNextLevelTradeItemWithinInne rPack	Quantity per package	n/a	n/a	n/a	n/a		
Depth & UOM	depth & MeasurementUnitCode_GDSN	n/a	n/a	5 INH	6 INH	17 INH		
Height & UOM	height & MeasurementUnitCode_GDSN	n/a	n/a	2.5 INH	9 INH	10 INH		
Width & UOM	width & MeasurementUnitCode_GDSN	n/a	n/a	8 INH	9 INH	16 INH		
Gross Weight & UOM	grossWeight & MeasurementUnitCode_GDSN	n/a	n/a	6 ONZ	18.5 ONZ	7.2 LBR		
Additional Classification Agency	AdditionalTradeItemClassificationCodeList Code	FDA Premarke t Submissio n Number	n/a	5 (UNSPC)	5 (UNSPC)	5 (UNSPC)		
Additional Classification Category Code	additionalClassificationCategoryCode	FDA Premarke t Submissio n Number	n/a	42192420	42192420	42192420		
Additional Classification Version	additionalClassificationCategoryCodeVersi on	n/a	n/a	23	23.0701	23.0701		
Packaging Type Code	PackageTypeCode_GDSN	Package Type	n/a	MPG (Multipack)	BG (Bag)	CS (case)		
Publication Date	publicationDateTime	n/a	n/a	n/a	n/a	n/a		
Established Name	regulatedProductName	n/a	n/a	n/a	n/a	n/a		
Start Availability Date/Time	startAvailabilityDateTime	n/a	n/a	n/a	n/a	n/a		
Trade Item Status	a 'command' to be added by Data Pool	n/a	n/a	ADD	ADD	ADD		



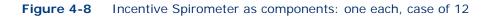




 Table 4-8
 Incentive Spirometer as components: one each, case of 12

			Packaging Level		
Common Name	GDSN Attribute	GUDI D Data Element	Each	Case	
Product Description	tradeItemDescription	Device Description	Spirometer Incentive 5000 ml 1/EA	Spirometer Incentive 5000 ml CS/12 1/EA NET QTY 12	
Product Identifier, GTIN	globalTradeItemNumber (GTIN)	DI (device identifier)	GTIN A	GTIN B	
Brand Name	brandName	Brand Name	Healthcare Products	Healthcare Products	
Global Product Category (GPC) Code	gpcCategoryCode	n/a	10005844	10005844	
Net Content & UoM	netContent (& UOM)	Device Count / Quantity per Package	1 EA	12 EA	
Country of Sale / Target Market	targetMarketCountryCode	n/a	001	001	
Child Trade Item	tradeItemIdentificationOfNextLowerLevelTradeItem (GTIN)	n/a	n/a	GTIN A	
Count of Each Specific Product	quantityOfNextLowerLevelTradeItem	n/a	n/a	12	
			1 Spirometer Body Assembly		
Unit of Use DI	componentIdentification	Unit of Use DI, Kit or Combination Product (refer to FDA guidance)	1 Tube Mouthpiece Assembly	n/a	
		(ioioi to i birigaladhioo)	1 Flex Tube		
Unit Descriptor	TradeItemUnitDescriptorCode	n/a	BASE_UNIT_OR_EACH	CASE	
Name of Information Provider	partyName	n/a	Healthcare Products Inc	Healthcare Products Inc	
GLN of Information Provider	gln (info provider)	n/a 0614141000005		0614141000005	
Orderable Unit Indicator	isTradeItemAnOrderableUnit	n/a	FALSE	TRUE	
Base Unit Indicator	isTradeItemABaseUnit	n/a	TRUE	FALSE	



C			Packaging Level	
Common Name	GDSN Attribute	GUDID Data Element	Each	Case
Additional Product Identifier Code	AdditionalTradeItemIdentificationTypeCode	Version or Model Number	SUPPLIER_ASSIGNED	SUPPLIER_ASSIGNED
Additional Product Identifier	additionalTradeItemIdentificationValue	Version or Model Number	SPIR5000	SPIR5000CS12
Manufacturer Name	partyName (mfg name)	n/a	Healthcare Products Inc	Healthcare Products Inc
Manufacturer GLN	gln (mfg)	n/a	0614141000005	0614141000005
Functional Name	functionalName	n/a	Incentive Spirometer	Incentive Spirometer
Number of Different Products	quantityOfChildren	n/a	n/a	1
Total Count of All Products	totalQuantityOfNextLowerLevelTradeItem	n/a	n/a	12
Consumer Unit Indicator	isTradeItemAConsumerUnit	n/a	TRUE	FALSE
Invoice Unit Indicator	isTradeItemAnInvoiceUnit	n/a	FALSE	TRUE
Shipping Unit Indicator	isTradeItemADespatchUnit	n/a	FALSE	TRUE
Variable Measure Unit Indicator	isTradeItemAVariableUnit	n/a	FALSE	FALSE
Effective Date	effectiveDateTime	being researched	2021-01-01T04:00:00Z	2021-01- 01T04:00:00Z
End Availability Date/Time	endAvailabilityDateTime	n/a	n/a	n/a
Dosage Form Type	dosageFormTypeCodeReference	n/a	n/a	n/a
Ingredient Strength	ingredientStrength	n/a	n/a	n/a
Data Carrier Type Code	DataCarrierTypeCode	n/a	GS1_DATA_MATRIX	GS1-128
Serial Number Location Code	SerialNumberLocationCode	Serial Number	NOT_MARKED	NOT_MARKED
Has Batch Number	hasBatchNumber	Lot or Batch Number	FALSE	FALSE
Trade Item Date on Packaging Code	tradeItemDateOnPackagingTypeCode	By Expiration Date	EXPIRATION_DATE	EXPIRATION_DATE
Quantity of Inner Pack	quantityOfInnerPack	n/a	n/a	n/a
Quantity of Next Level Trade Item within Inner Pack	quantityOfNextLevelTradeItemWithinInnerPack	Quantity per package	n/a	n/a
Depth & UOM	depth & MeasurementUnitCode_GDSN	n/a	10 INH	20 INH
Height & UOM	height & MeasurementUnitCode_GDSN	n/a	7 INH	7 INH
Width & UOM	width & MeasurementUnitCode_GDSN	n/a	3 INH	18 INH
Gross Weight & UOM	grossWeight & MeasurementUnitCode_GDSN	n/a	12 ONZ	9 LBR
Additional Classification Agency	AdditionalTradeItemClassificationSystemCode	FDA Premarket Submission Number (58)	5 (UNSPSC)	5 (UNSPSC)



Common Name	GDSN Attribute	GUDID Data Element	Packaging Level		
common Name		GODI D Data Element	Each	Case	
Additional Classification Category Code	additionalTradeItemClassificationCodeValue	FDA Premarket Submission Number	41100000	41100000	
Additional Classification Version	additionalClassificationCategoryCodeVersion	n/a	23.0701	23.0701	
Packaging Type Code	PackageTypeCode_GDSN	Package Type	BG (bag)	CS (case)	
Publication Date	publicationDateTime	n/a	n/a	n/a	
Established Name	regulatedProductName	n/a	n/a	n/a	
Start Availability Date/Time	startAvailabilityDateTime	n/a	2021-04-01T04:00:00Z	2021-04- 01T04:00:00Z	
Trade Item Status	a 'command' to be added by Data Pool	n/a	ADD	ADD	



Figure 4-9 Generic Medication: Three hierarchy examples

- Unmarked capsule, bottle of 500 capsules, case of 6 bottles
- Unmarked blister cell, marked card of 5 blister cells, box of 3 cards, case of 12 boxes
- Marked blister cell, marked card of 5 marked blister cells, box of 3 cards, case of 12 boxes

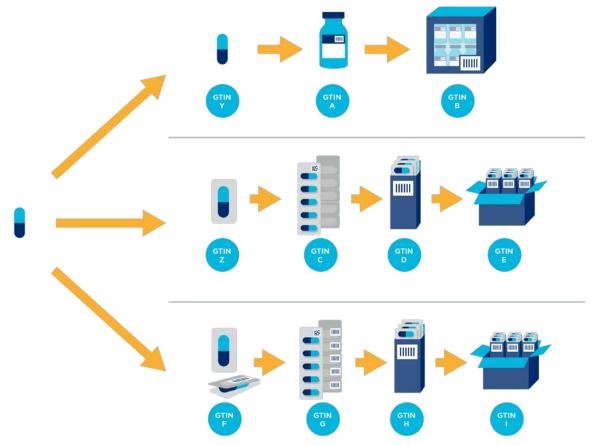


 Table 4-9
 Generic Medication: unmarked capsule, bottle of 500 capsules, case of 6

		GUDID	Packaging Level				
Common Name	GDSN Attribute	Data Element	Unit of Use	Base Unit	Inner Pack	Case	
Product Description	tradeItemDescription	Device Descriptio n	n/a	Generic Medication 100 mg Tablet BO/500 NET QTY 500	n/a	Generic Medication 100 mg Tablet CA/6 BO/500 NET QTY 3000	
Product Identifier, GTIN	globalTradeItemNumber (GTIN)	DI (device identifier)	GTIN Y	GTIN A	n/a	GTIN B	
Brand Name	brandName	Brand Name	n/a	unbranded	n/a	unbranded	
Global Product Category (GPC) Code	gpcCategoryCode	n/a	n/a	10005845	n/a	10005845	



		GUDID	Packaging	Packaging Level			
Common Name	GDSN Attribute	Data Element	Unit of Use	Base Unit	Inner Pack	Case	
Net Content & UoM	netContent (& UOM)	Device Count / Quantity per Package	n/a	500 EA	n/a	3000 EA	
Country of Sale / Target Market	targetMarketCountryCode	n/a	n/a	001	n/a	001	
Child Trade Item	tradeItemIdentificationOfNextLowerLevelTrad eItem (GTIN)	n/a	n/a	n/a	n/a	GTIN A	
Count of Each Specific Product	quantityOfNextLowerLevelTradeItem	n/a	n/a	n/a	n/a	500	
Unit of Use DI	componentIdentification	Unit of Use DI Number	n/a	GTIN Y	n/a	n/a	
Unit Descriptor	TradeItemUnitDescriptorCode	n/a	n/a	BASE_UNIT_OR_EA CH	n/a	CASE	
Name of Information Provider	partyName	n/a	n/a	Pharma Products Inc	n/a	Pharma Products Inc	
GLN of Information Provider	gln (info provider)	n/a	n/a	0614141000029	n/a	0614141000029	
Orderable Unit Indicator	isTradeItemAnOrderableUnit	n/a	n/a	TRUE	n/a	TRUE	
Base Unit Indicator	isTradeItemABaseUnit	n/a	n/a	TRUE	n/a	FALSE	
Additional Product Identifier Code	AdditionalTradeItemIdentificationTypeCode	Version or Model Number	n/a	FDA_NDC_10	n/a	FDA_NDC_10	
Additional Product Identifier	additionalTradeItemIdentificationValue	Version or Model Number	n/a	NDC A	n/a	NDC A	
Manufacturer Name	partyName (mfg name)	n/a	n/a	Pharma Products Inc	n/a	Pharma Products Inc	
Manufacturer GLN	gln (mfg)	n/a	n/a	0614141000029	n/a	0614141000029	
Functional Name	functionalName	n/a	n/a	Generic Medication 100MG	n/a	Generic Medication 100MG	
Number of Different Products	quantityOfChildren	n/a	n/a	n/a	n/a	1	
Total Count of All Products	totalQuantityOfNextLowerLevelTradeItem	n/a	n/a	n/a	n/a	6	
Consumer Unit Indicator	isTradeItemAConsumerUnit	n/a	n/a	FALSE	n/a	FALSE	
Invoice Unit Indicator	isTradeItemAnInvoiceUnit	n/a	n/a	TRUE	n/a	TRUE	
Shipping Unit Indicator	isTradeItemADespatchUnit	n/a	n/a	TRUE	n/a	TRUE	
Variable Measure Unit Indicator	isTradeItemAVariableUnit	n/a	n/a	FALSE	n/a	FALSE	



		GUDID	Packaging	Packaging Level			
Common Name	GDSN Attribute	Data Element	Unit of Use	Base Unit	Inner Pack	Case	
Effective Date	effectiveDateTime	being researche d	n/a	2020-01- 01T04:00:00Z	n/a	2020-01- 01T04:00:00Z	
End Availability Date/Time	endAvailabilityDateTime	n/a	n/a	9999-12- 31T23:59:59Z	n/a	9999-12- 31T23:59:59Z	
Dosage Form Type	dosageFormTypeCodeReference	n/a	n/a	CAPSULE	n/a	CAPSULE	
Ingredient Strength	ingredientStrength	n/a	n/a	100 MG	n/a	100 MG	
Data Carrier Type Code	DataCarrierTypeCode	n/a	n/a	GS1_128	n/a	GS1_128	
Serial Number Location Code	SerialNumberLocationCode	Serial Number	n/a	MARKED ON PACKAGING	n/a	MARKED ON PACKAGING	
Has Batch Number	hasBatchNumber	Lot or Batch Number	n/a	TRUE	n/a	TRUE	
Trade Item Date on Packaging Code	tradeItemDateOnPackagingTypeCode	By Expiration Date	n/a	EXPIRATION_DATE	n/a	EXPIRATION_DA TE	
Quantity of Inner Pack	quantityOfInnerPack	n/a	n/a	n/a	n/a	n/a	
Quantity of Next Level Trade Item within Inner Pack	quantityOfNextLevelTradeItemWithinInnerPac k	Quantity per package	n/a	n/a	n/a	n/a	
Depth & UOM	depth & MeasurementUnitCode_GDSN	n/a	n/a	3.08	n/a	9.5 INH	
Height & UOM	height & MeasurementUnitCode_GDSN	n/a	n/a	5.25 INH	n/a	5.5 INH	
Width & UOM	width & MeasurementUnitCode_GDSN	n/a	n/a	3.08 INH	n/a	6.25 INH	
Gross Weight & UOM	grossWeight & MeasurementUnitCode_GDSN	n/a	n/a	340 GRM	n/a	2100 GRM	
Additional Classification Agency	AdditionalTradeItemClassificationCodeListCod e	FDA Premarke t Submissio n Number	n/a	5 (UNSPC)	n/a	5 (UNSPSC)	
Additional Classification Category Code	additionalClassificationCategoryCode	FDA Premarke t Submissio n Number	n/a	51362601	n/a	51362601	
Additional Classification Version	additionalClassificationCategoryCodeVersion	n/a	n/a	23.0701	n/a	23.0701	
Packaging Type Code	PackageTypeCode_GDSN	Package Type	n/a	во	n/a	CS(Case)	
Publication Date	publicationDateTime	n/a	n/a	2020-01- 01T04:00:00Z	n/a n/a	2020-01- 01T04:00:00Z	
Established Name	regulatedProductName	n/a	n/a	9999-12- 31T23:59:59Z	n/a	9999-12- 31T23:59:59Z	



	Common	GUDID	Packaging Level			
Common Name	GDSN Attribute	GUDID Data Element n/a	Unit of Use	Base Unit	Inner Pack	Case
Start Availability Date/Time	startAvailabilityDateTime	n/a	n/a	2020-01- 01T04:00:00Z	n/a	2020-01- 01T04:00:00Z
Trade Item Status	a 'command' to be added by Data Pool	n/a	n/a	ADD	n/a	ADD

Table 4-9.1Generic Medication: unmarked blister cell, marked card of 5 blister cells, box of 3 cards,
case of 12 boxes

0		GUDID	Packaging Lev	/el	-	
Common Name	GDSN Attribute	Data Element	Unit of Use	Base Unit	Inner Pack	Case
Product Description	tradel temDescription	Device Descripti on	n/a	Generic Medication 100 mg Tablet CG/5 NET QTY 5	Generic Medication 100 mg BX/3 CG/5 NET QTY 15	Generic Medication 100 mg Tablet CA/12 BX/3 CG/5 NET QTY 180
Product Identifier, GTIN	globalTradeItemNumber (GTIN)	DI (device identifier)	GTIN Z	GTIN C	GTIN D	GTIN E
Brand Name	brandName	Brand Name	n/a	unbranded	unbranded	unbranded
Global Product Category (GPC) Code	gpcCategoryCode	n/a	n/a	10005845	10005845	10005845
Net Content & UoM	netContent (& UOM)	Device Count / Quantity per Package	n/a	5 EA; 1 CG	15 EA; 3 CG	180 EA; 36 CG
Country of Sale / Target Market	targetMarketCountryCode	n/a	n/a	001	001	001
Child Trade Item	tradeItemIdentificationOfNextLowerLevel TradeItem (GTIN)	n/a	n/a	n/a	GTIN C	GTIN D
Count of Each Specific Product	quantityOfNextLowerLevelTradeItem	n/a	n/a	5	3	12
Unit of Use DI	componentIdentification	Unit of Use DI Number	n/a	GTIN Z		
Unit Descriptor	TradeItemUnitDescriptorCode	n/a	n/a	BASE_UNIT_OR_ EACH	PACK_OR_INNER_ PACK	CASE
Name of Information Provider	partyName	n/a	n/a	Pharma Products Inc	Pharma Products Inc	Pharma Products Inc
GLN of Information Provider	gln (info provider)	n/a	n/a	0614141000029	0614141000029	061414100002 9
Orderable Unit Indicator	isTradeItemAnOrderableUnit	n/a	n/a	FALSE	TRUE	TRUE



		GUDID	Packaging Level				
Common Name	GDSN Attribute	Data Element	Unit of Use	Base Unit	Inner Pack	Case	
Base Unit Indicator	isTradeItemABaseUnit	n/a	n/a	TRUE	FALSE	FALSE	
Additional Product Identifier Code	AdditionalTradeItemIdentificationTypeCo de	Version or Model Number	n/a	FDA_NDC_10	FDA_NDC_10	FDA_NDC_10	
Additional Product Identifier	additionalTradeItemIdentificationValue	Version or Model Number	n/a	NDC B	NDC B	NDC B	
Manufacturer Name	partyName (mfg name)	n/a	n/a	Pharma Products Inc	Pharma Products Inc	Pharma Products Inc	
Manufacturer GLN	gln (mfg)	n/a	n/a	0614141000029	0614141000029	061414100002 9	
Functional Name	functionalName	n/a	n/a	Generic Medication 100MG	Generic Medication 100MG	Generic Medication 100MG	
Number of Different Products	quantityOfChildren	n/a	n/a	n/a	1	1	
Total Count of All Products	totalQuantityOfNextLowerLevelTradeIte m	n/a	n/a	5	3	12	
Consumer Unit Indicator	isTradeItemAConsumerUnit	n/a	n/a	TRUE	TRUE	FALSE	
Invoice Unit Indicator	isTradeItemAnInvoiceUnit	n/a	n/a	FALSE	FALSE	TRUE	
Shipping Unit Indicator	isTradeItemADespatchUnit	n/a	n/a	FALSE	FALSE	TRUE	
Variable Measure Unit Indicator	isTradeItemAVariableUnit	n/a	n/a	FALSE	FALSE	FALSE	
Effective Date	effectiveDateTime	being research ed	n/a	2020-01- 01T04:00:00Z	2020-01- 01T04:00:00Z	2020-01- 01T04:00:00Z	
End Availability Date/Time	endAvailabilityDateTime	n/a	n/a	9999-12- 31T23:59:59Z	9999-12- 31T23:59:59Z	9999-12- 31T23:59:59Z	
Dosage Form Type	dosageFormTypeCodeReference	n/a	n/a	CAPSULE	CAPSULE	CAPSULE	
Ingredient Strength	ingredientStrength	n/a	n/a	100 MG	100 MG	100 MG	
Data Carrier Type Code	DataCarrierTypeCode	n/a	n/a	GS1_DATA_MATR IX	GS1_DATA_MATRI X	GS1_DATA_MA TRIX	
Serial Number Location Code	SerialNumberLocationCode	Serial Number	n/a	MARKED ON PACKAGING	MARKED ON PACKAGING	MARKED ON PACKAGING	
Has Batch Number	hasBatchNumber	Lot or Batch Number	n/a	TRUE	TRUE	TRUE	
Trade Item Date on Packaging Code	tradeItemDateOnPackagingTypeCode	By Expiratio n Date	n/a	EXPIRATION_DAT E	EXPIRATION_DATE	EXPIRATION_D ATE	



		GUDID	Packaging Lev	Packaging Level				
Common Name	GDSN Attribute	Data Element	Unit of Use	Base Unit	Inner Pack	Case		
Quantity of Inner Pack	quantityOfInnerPack	n/a	n/a	n/a	n/a	n/a		
Quantity of Next Level Trade Item within Inner Pack	quantityOfNextLevelTradeItemWithinInn erPack	Quantity per package	n/a	n/a	n/a	n/a		
Depth & UOM	depth & MeasurementUnitCode_GDSN	n/a	n/a	8 CMT	13 CMT	46 CMT		
Height & UOM	height & MeasurementUnitCode_GDSN	n/a	n/a	1 CMT	9 CMT	12 CMT		
Width & UOM	width & MeasurementUnitCode_GDSN	n/a	n/a	10 CMT	11 CMT	27 CMT		
Gross Weight & UOM	grossWeight & MeasurementUnitCode_GDSN	n/a	n/a	15 GRM	190 GRM	2000 GRM		
Additional Classification Agency	AdditionalTradeItemClassificationCodeLis tCode	FDA Premark et Submissi on Number	n/a	5 (UNSPC)	5 (UNSPSC)	5 (UNSPSC)		
Additional Classification Category Code	additionalClassificationCategoryCode	FDA Premark et Submissi on Number	n/a	51362601	51362601	51362601		
Additional Classification Version	additionalClassificationCategoryCodeVers ion	n/a	n/a	23.0701		23.0701		
Packaging Type Code	PackageTypeCode_GDSN	Package Type	n/a		вх	CS(Case)		
Publication Date	publicationDateTime	n/a	n/a	2020-01- 01T04:00:00Z	2020-01- 01T04:00:00Z	2020-01- 01T04:00:00Z		
Established Name	regulatedProductName	n/a	n/a	9999-12- 31T23:59:59Z	9999-12- 31T23:59:59Z	9999-12- 31T23:59:59Z		
Start Availability Date/Time	startAvailabilityDateTime	n/a	n/a	2020-01- 01T04:00:00Z	2020-01- 01T04:00:00Z	2020-01- 01T04:00:00Z		
Trade Item Status	a 'command' to be added by Data Pool	n/a	n/a	ADD	ADD	ADD		

Table 4-9.2Generic medication: marked blister cell, marked card of 5 marked blister cells, box of 3
cards, case of 12 boxes

0		GUDID	Packaging Level			
Common Name	GDSN Attribute	Data Element	Unit of Use	Base Unit	Inner Pack	Case
Product Description	tradeItemDescription	Device Description	Generic Medication 100 mg Tablet 1EA	Generic Medication 100 mg Tablet CG/5 NET QTY 5	Generic Medication 100 mg BX/3 CG/5 NET QTY 15	Generic Medication 100 mg Tablet CA/12 BX/3 CG/5 NET QTY 180



		GUDID	Packaging Level				
Common Name	GDSN Attribute	Data Element	Unit of Use	Base Unit	Inner Pack	Case	
Product Identifier, GTIN	globalTradeItemNumber (GTIN)	DI (device identifier)	GTIN F	GTIN G	GTIN H	GTIN I	
Brand Name	brandName	Brand Name	unbranded	unbranded	unbranded	unbranded	
Global Product Category (GPC) Code	gpcCategoryCode	n/a	10005845	10005845	10005845	10005845	
Net Content & UoM	netContent (& UOM)	Device Count / Quantity per Package	1 EA	5 EA; 1 CG	15 EA; 3 CG	180 EA; 36 CG	
Country of Sale / Target Market	targetMarketCountryCode	n/a	001	001	001	001	
Child Trade Item	tradeItemIdentificationOfNextLowerLe velTradeItem (GTIN)	n/a	n/a	GTIN F	GTIN G	GTIN H	
Count of Each Specific Product	quantityOfNextLowerLevelTradeItem	n/a	n/a	5	3	12	
Unit of Use DI	componentIdentification	Unit of Use DI Number	n/a	n/a	n/a	n/a	
Unit Descriptor	TradeItemUnitDescriptorCode	n/a	BASE_UNIT_O R_EACH	PACK_OR_INNER _PACK	PACK_OR_INNER _PACK	CASE	
Name of Information Provider	partyName	n/a	Pharma Products Inc	Pharma Products Inc	Pharma Products Inc	Pharma Products Inc	
GLN of Information Provider	gln (info provider)	n/a	06141410000 29	0614141000029	0614141000029	06141410000 29	
Orderable Unit Indicator	isTradeItemAnOrderableUnit	n/a	FALSE	FALSE	TRUE	TRUE	
Base Unit Indicator	isTradeItemABaseUnit	n/a	TRUE	FALSE	FALSE	FALSE	
Additional Product Identifier Code	AdditionalTradeItemIdentificationType Code	Version or Model Number	FDA_NDC_10	FDA_NDC_10	FDA_NDC_10	FDA_NDC_10	
Additional Product Identifier	additionalTradeItemIdentificationValue	Version or Model Number	NDC C	NDC C	NDC C	NDC C	
Manufacture r Name	partyName (mfg name)	n/a	Pharma Products Inc	Pharma Products Inc	Pharma Products Inc	Pharma Products Inc	
Manufacture r GLN	gln (mfg)	n/a	06141410000 29	0614141000029	0614141000029	06141410000 29	
Functional Name	functionalName	n/a	Generic Medication 100MG	Generic Medication 100MG	Generic Medication 100MG	Generic Medication 100MG	
Number of Different Products	quantityOfChildren	n/a	n/a	1	1	1	
Total Count of All Products	totalQuantityOfNextLowerLevelTradeIt em	n/a	n/a	5	3	12	



Common Name	GDSN Attribute	GUDID Data Element	Packaging Level				
			Unit of Use	Base Unit	Inner Pack	Case	
Consumer Unit Indicator	isTradeItemAConsumerUnit	n/a	TRUE	TRUE	FALSE	FALSE	
Invoice Unit Indicator	isTradeItemAnInvoiceUnit	n/a	FALSE	FALSE	TRUE	TRUE	
Shipping Unit Indicator	isTradeItemADespatchUnit	n/a	FALSE	FALSE	TRUE	TRUE	
Variable Measure Unit Indicator	isTradeItemAVariableUnit	n/a	FALSE	FALSE	FALSE	FALSE	
Effective Date	effectiveDateTime	being researched	2020-01- 01T04:00:00Z	2020-01- 01T04:00:00Z	2020-01- 01T04:00:00Z	2020-01- 01T04:00:00Z	
End Availability Date/Time	endAvailabilityDateTime	n/a	9999-12- 31T23:59:59Z	9999-12- 31T23:59:59Z	9999-12- 31T23:59:59Z	9999-12- 31T23:59:59Z	
Dosage Form Type	dosageFormTypeCodeReference	n/a	CAPSULE	CAPSULE	CAPSULE	CAPSULE	
Ingredient Strength	ingredientStrength	n/a	100 MG	100 MG	100 MG	100 MG	
Data Carrier Type Code	DataCarrierTypeCode	n/a	GS1_DATA_M ATRIX	GS1_DATA_MATR IX	GS1_DATA_MATR IX	GS1_DATA_M ATRIX	
Serial Number Location Code	SerialNumberLocationCode	Serial Number	MARKED_ON_ PACKAGING	MARKED ON PACKAGING	MARKED ON PACKAGING	MARKED ON PACKAGING	
Has Batch Number	hasBatchNumber	Lot or Batch Number	TRUE	TRUE	TRUE	TRUE	
Trade Item Date on Packaging Code	tradeItemDateOnPackagingTypeCode	By Expiration Date	EXPIRATION_ DATE	EXPIRATION_DAT E	EXPIRATION_DAT E	EXPIRATION_ DATE	
Quantity of Inner Pack	quantityOfInnerPack	n/a	n/a	n/a	n/a	n/a	
Quantity of Next Level Trade Item within Inner Pack	quantityOfNextLevelTradeItemWithinI nnerPack	Quantity per package	n/a	n/a	n/a	n/a	
Depth & UOM	depth & MeasurementUnitCode_GDSN	n/a	n/a	8 CMT	13 CMT	46 CMT	
Height & UOM	height & MeasurementUnitCode_GDSN	n/a	n/a	1 CMT	9 CMT	12 CMT	
Width & UOM	width & MeasurementUnitCode_GDSN	n/a	n/a	10 CMT	11 CMT	27 CMT	
Gross Weight & UOM	grossWeight & MeasurementUnitCode_GDSN	n/a	n/a	15 GRM	190 GRM	2000 GRM	
Additional Classificatio n Agency	AdditionalTradeItemClassificationCode ListCode	FDA Premarket Submission Number	n/a	5 (UNSPC)	5 (UNSPSC)	5 (UNSPSC)	
Additional Classificatio n Category Code	additionalClassificationCategoryCode	FDA Premarket Submission Number	n/a	51362601	51362601	51362601	
Additional Classificatio n Version	additionalClassificationCategoryCodeV ersion	n/a	n/a	23.0701		23.0701	



Common Name	GDSN Attribute	GUDID Data Element	Packaging Level				
			Unit of Use	Base Unit	Inner Pack	Case	
Packaging Type Code	PackageTypeCode_GDSN	Package Type	n/a	n/a	вх	CS(Case)	
Publication Date	publicationDateTime	n/a	n/a	2020-01- 01T04:00:00Z	2020-01- 01T04:00:00Z	2020-01- 01T04:00:00Z	
Established Name	regulatedProductName	n/a	n/a	9999-12- 31T23:59:59Z	9999-12- 31T23:59:59Z	9999-12- 31T23:59:59Z	
Start Availability Date/Time	startAvailabilityDateTime	n/a	n/a	2020-01- 01T04:00:00Z	2020-01- 01T04:00:00Z	2020-01- 01T04:00:00Z	
Trade Item Status	a 'command' to be added by Data Pool	n/a	n/a	ADD	ADD	ADD	



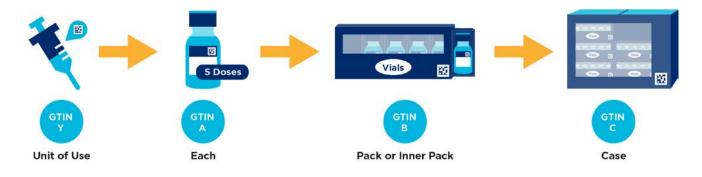


Figure 4-10 Flu Vaccine: 5ml multidose vial, Box of 5 vials, case of 5 boxes



Common Name	GDSN Attribute	GUDI D Data Element	Packaging Level				
			Unit of Use	Base Unit	Inner Pack	Case	
Product Description	tradeItemDescription	Device Descriptio n	n/a	Influenza Vaccine 5ml Multi Dose VI/5ml NET QTY 5ml =10 doses of 0.5ml	Influenza Vaccine 5ml Multi Dose Vial PK/5 VI/5ml NET QTY 25ml = 50 doses of 0.5ml	Influenza Vaccine 5ml Multi Dose Vial, CA/5 PK/5 VI/5ml NET QTY 125ml = 250 doses of 0.5ml	
Product Identifier, GTIN	globalTradeItemNumber (GTIN)	DI (device identifier)	n/a	GTIN A	GTIN B	GTIN C	
Brand Name	brandName	Brand Name	n/a	unbranded	unbranded	unbranded	
Global Product Category (GPC) Code	gpcCategoryCode	n/a	n/a	10005845	10005845	10005845	
Net Content & UoM	netContent (& UOM)	Device Count / Quantity per Package	n/a	10 doses; 5ml	50 doses; 25ml	250 doses; 125ml	
Country of Sale / Target Market	targetMarketCountryCode	n/a	n/a	001	001	001	
Child Trade Item	tradeItemIdentificationOfNextLowerLevelTra deItem (GTIN)	n/a	n/a	n/a	GTIN A	GTIN B	
Count of Each Specific Product	quantityOfNextLowerLevelTradeItem	n/a	n/a	n/a	5	5	
Unit of Use DI	componentIdentification	Unit of Use DI Number	n/a	n/a	n/a	n/a	
Unit Descriptor	TradeItemUnitDescriptorCode	n/a	n/a	BASE_UNIT_OR_E ACH	PACK_OR_INNER_P ACK	CASE	



Common Name	GDSN Attribute	GUDI D Data Element	Packaging Level				
			Unit of Use	Base Unit	Inner Pack	Case	
Name of Informatio n Provider	partyName	n/a	n/a	Pharma Products Inc	Pharma Products Inc	Pharma Products Inc	
GLN of Informatio n Provider	gln (info provider)	n/a	n/a	0614141000029	0614141000029	0614141000029	
Orderable Unit Indicator	isTradeItemAnOrderableUnit	n/a	n/a	FALSE	TRUE	TRUE	
Base Unit Indicator	isTradeItemABaseUnit	n/a	n/a	TRUE	FALSE	FALSE	
Additional Product Identifier Code	AdditionalTradeItemIdentificationTypeCode	Version or Model Number	n/a	FDA_NDC_10	FDA_NDC_10	FDA_NDC_10	
Additional Product Identifier	additionalTradeItemIdentificationValue	Version or Model Number	n/a	NDC C	NDC B	NDC A	
Manufactur er Name	partyName (mfg name)	n/a	n/a	Pharma Products Inc	Pharma Products Inc	Pharma Products Inc	
Manufactur er GLN	gln (mfg)	n/a	n/a	0614141000029	0614141000029	0614141000029	
Functional Name	functionalName	n/a	n/a	Seasonal Flu Vaccine	Seasonal Flu Vaccine	Seasonal Flu Vaccine	
Number of Different Products	quantityOfChildren	n/a	n/a	n/a	1	1	
Total Count of All Products	totalQuantityOfNextLowerLevelTradeItem	n/a	n/a		5	5	
Consumer Unit Indicator	isTradeItemAConsumerUnit	n/a	n/a	TRUE	TRUE	FALSE	
Invoice Unit Indicator	isTradeItemAnInvoiceUnit	n/a	n/a	FALSE	TRUE	TRUE	
Shipping Unit Indicator	isTradeItemADespatchUnit	n/a	n/a	FALSE	TRUE	TRUE	
Variable Measure Unit Indicator	isTradeItemAVariableUnit	n/a	n/a	FALSE	FALSE	FALSE	
Effective Date	effectiveDateTime	n/a	n/a	2020-01- 01T04:00:00Z	2020-01- 01T04:00:00Z	2020-01- 01T04:00:00Z	
End Availability Date/Time	endAvailabilityDateTime	n/a	n/a	n/a	n/a	n/a	
Dosage Form Type	dosageFormTypeCodeReference	n/a	n/a	INJECTION, SUSPENSION	INJECTION, SUSPENSION	INJECTION, SUSPENSION	
Ingredient Strength	ingredientStrength	n/a	n/a	60 mcg HA per 5 ml dose	60 mcg HA per 5 ml dose	60 mcg HA per 5 ml dose	
Data Carrier Type Code	DataCarrierTypeCode	n/a	n/a	GS1_DATA_MATRI X	GS1_DATA_MATRIX	GS1_DATA_MAT RIX	
Serial Number Location Code	SerialNumberLocationCode	Serial Number	n/a	MARKED ON TRADE ITEM	MARKED ON PACKAGING	MARKED ON PACKAGING	
Has Batch Number	hasBatchNumber	Lot or Batch Number	n/a	TRUE	TRUE	TRUE	



Common Name	GDSN Attribute	GUDI D Data Element	Packaging Level				
			Unit of Use	Base Unit	Inner Pack	Case	
Trade Item Date on Packaging Code	tradeltemDateOnPackagingTypeCode	By Expiratio n Date	n/a	EXPIRATION_DATE	EXPIRATION_DATE	EXPIRATION_DA TE	
Quantity of Inner Pack	quantityOfInnerPack	n/a	n/a	n/a	n/a	n/a	
Quantity of Next Level Trade Item within Inner Pack	quantityOfNextLevelTradeItemWithinInnerPa ck	Quantity per package	n/a	n/a	n/a	n/a	
Depth & UOM	depth & MeasurementUnitCode_GDSN	n/a	n/a	1.12 INH	1.38 INH	5.625 INH	
Height & UOM	height & MeasurementUnitCode_GDSN	n/a	n/a	2.75 INH	3.0 INH	3.0 INH	
Width & UOM	width & MeasurementUnitCode_GDSN	n/a	n/a	1.12 INH	5.625 INH	5.625 INH	
Gross Weight & UOM	grossWeight & MeasurementUnitCode_GDSN	n/a	n/a	.75 ONZ	4.0 ONZ	21.5 ONZ	
Additional Classificati on Agency	AdditionalTradeItemClassificationCodeListCo de	FDA Premarke t Submissi on Number	n/a	5 (UNSPC)	5 (UNSPC)	5 (UNSPC)	
Additional Classificati on Category Code	additionalClassificationCategoryCode	FDA Premarke t Submissi on Number	n/a	51201608	51201608	51201608	
Additional Classificati on Version	additionalClassificationCategoryCodeVersion	n/a	n/a	23.0701	23.0701	23.0701	
Packaging Type Code	PackageTypeCode_GDSN	Package Type	n/a	во	вх	CS(Case)	
Publication Date	publicationDateTime	n/a	n/a	2020-01- 01T04:00:00Z	2020-01- 01T04:00:00Z	2020-01- 01T04:00:00Z	
Established Name	regulatedProductName	n/a	n/a				
Start Availability Date/Time	startAvailabilityDateTime	n/a	n/a	2020-01- 01T04:00:00Z	2020-01- 01T04:00:00Z	2020-01- 01T04:00:00Z	
Trade Item Status	a 'command' to be added by Data Pool	n/a	n/a	ADD	ADD	ADD	



5 Resources List

For more guidance and updated references for these and other topics, please see the following additional resources:

Global Standards Resources

<u>GS1 Attribute Definitions for Business Standard</u> <u>GDSN 3.1 Trade Item Implementation Guide</u>

GDSN and Shared Code List

GDSN Trade Item Module Library Business Message Standard

GDSN Package Measurement Rules

<u>Pharmaceutical Serialization and Traceability Use Case - Enable the sharing of pharmaceutical product</u> <u>information via the GDSN</u>

GS1 US Resources

Implementation Guideline - Applying the GS1 System of Standards for U.S. FDA Unique Device Identification (UDI)

Other Resources

ISMP error prone abbreviations list Unit of Use (UOU) Explained - Why it Exists and Best Practices for Creation U.S. FDA Dosage Forms U.S. FDA GUDID Guidance



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