



The Global Language of Business

# Medical Devices GDS Context Report

-

*Release 3.1, Draft, Aug 2015*

---

## Document Summary

Document Item	Current Value
Document Name	Medical Devices GDS Context Report
Document Date	Aug 2015
Document Version	3.1
Document Issue	2.0
Document Status	Draft
Document Description	-

## Work Request Reference

Date of WR Submission	Submitter(s):	Refer to Work Request Number(s):

## Business Requirements Document (BRAD) Reference

BRAD Title:	BRD Date:	BRAD Version

## Contributors

Name	Organisation
Steve Robba	1WorldSync
Robin Kidd	Nestle
Scott Brown	GS1 US
Mickey Atkins	Ahold (USA)
Tom Eric Schmidt	August Storck KG
Alasdair Garbett	Autogrill Retail UK Ltd t/a WDF
Bekki Windsperger	Best Buy Co., Inc.
Ed Jesus	Chep
Craig Arseneau	Commport Communications Int'l Inc.
Nadine Radomski	Dean Foods Company
Patrick Roy	FSE, Inc.
Joy Schneck	General Mills, Inc.
Mitch Fortier	GS1 Australia
Mirna Utkovic	GS1 Australia
Stephan Wijnker	GS1 Australia
Kristel Lai	GS1 Canada
Rita Laur	GS1 Canada

Name	Organisation
Giovanni Biffi	GS1 Colombia
Jean-Luc Leblond	GS1 France
Tanja Thomsen	GS1 Germany
Justin Childs	GS1 Global Office
János Gyuris	GS1 Hungary
Krisztina Vatai	GS1 Hungary
Brendan Kernan	GS1 Ireland
Andrea Ausili	GS1 Italy
Federico Mittersteiner	GS1 Italy
Hideki Ichihara	GS1 Japan
Gabriel Sobrino	GS1 Netherlands
Leppie Kolwane	GS1 South Africa / Consumer Goods Council of South Africa
Xavier Pujol	GS1 Spain
Peter Jönsson	GS1 Sweden
Staffan Olsson	GS1 Sweden
Thanh Reichen	GS1 Switzerland
Neil Gray	GS1 UK
Shan Welch	GS1 UK
Tracey Davies	GXS (UK)
Joanna Stewart	GXS (US)
Rob Hoffman	Hershey Company (The)
Christine Nye	Hershey Company (The)
Eric Ginsburg	HJ Heinz
Betty Tyson	Knouse Foods Cooperative, Inc
Barbara Munro	Kraft Foods, Inc.
Ryan Richard	Kraft Foods, Inc.
Véra Feuerstein	Nestle
Joseph Bohning	Nestle Purina PetCare
Gina Tomassi	PepsiCo, Inc.
Sascha Kasper	SA2 Worldsync GmbH
Selcuk Ovuc	SA2 Worldsync GmbH
Maxim Stafeyev	SKB Kontur
Jason Lavik	Target Corporation
Phyllis Koch	The Schwan Food Company
Werner Kolb	Unilever N.V.
Audrey Wiggins	Wal-Mart Stores, Inc.
Mac Young	Waldo County General Hospital
Jan Jaworski	Wilton Industries, Inc.
Justin Childs	GS1 Global Office

Name	Organisation
Eric Kauz	GS1 Global Office
Mark Van Eeghem	GS1 Global Office

## Change Log

Date of Change	Version	Changed By	Reason for Change	Summary of Change
7-Jan-2013	0.0.1	Mark Van Eeghem	Initial Draft	n/a
30-Jan-2013	0.0.2	Mark Van Eeghem	Community Review	n/a
17-Jun-2013	1.0.0	Mark Van Eeghem	Comment resolution for Community Review	See section Summary Of Changes
31-Aug-2015	2.0	Mark Van Eeghem	Schema Drop September 2015	See Section Summary Of Changes

## Disclaimer

GS1<sup>®</sup>, under its IP Policy, seeks to avoid uncertainty regarding intellectual property claims by requiring the participants in the Work Group that developed this **Medical Devices GDS Context Report** to agree to grant to GS1 members a royalty-free licence or a RAND licence to Necessary Claims, as that term is defined in the GS1 IP Policy. Furthermore, attention is drawn to the possibility that an implementation of one or more features of this Specification may be the subject of a patent or other intellectual property right that does not involve a Necessary Claim. Any such patent or other intellectual property right is not subject to the licencing obligations of GS1. Moreover, the agreement to grant licences provided under the GS1 IP Policy does not include IP rights and any claims of third parties who were not participants in the Work Group.

Accordingly, GS1 recommends that any organization developing an implementation designed to be in conformance with this Specification should determine whether there are any patents that may encompass a specific implementation that the organisation is developing in compliance with the Specification and whether a licence under a patent or other intellectual property right is needed. Such a determination of a need for licencing should be made in view of the details of the specific system designed by the organisation in consultation with their own patent counsel.

THIS DOCUMENT IS PROVIDED "AS IS" WITH NO WARRANTIES WHATSOEVER, INCLUDING ANY WARRANTY OF MERCHANTABILITY, NONINFRINGEMENT, FITNESS FOR PARTICULAR PURPOSE, OR ANY WARRANTY OTHERWISE ARISING OUT OF THIS SPECIFICATION. GS1 disclaims all liability for any damages arising from use or misuse of this Standard, whether special, indirect, consequential, or compensatory damages, and including liability for infringement of any intellectual property rights, relating to use of information in or reliance upon this document.

GS1 retains the right to make changes to this document at any time, without notice. GS1 makes no warranty for the use of this document and assumes no responsibility for any errors which may appear in the document, nor does it make a commitment to update the information contained herein.

GS1 and the GS1 logo are registered trademarks of GS1 AISBL.

## Table of Contents

<b>1</b>	<b>Business Domain View .....</b>	<b>6</b>
1.1	Business Need .....	6
1.2	Objective .....	6
1.3	Audience .....	6
1.4	References .....	6
<b>2</b>	<b>Business Context.....</b>	<b>7</b>
<b>3</b>	<b>GPC Bricks included in the Medical Devices Context.....</b>	<b>8</b>
3.1	Bricks Included in Context.....	8
<b>4</b>	<b>Modules assigned to the Medical Devices Context.....</b>	<b>9</b>
<b>5</b>	<b>Enumerations and Code Lists referenced in the Medical Devices Context.....</b>	<b>10</b>
5.1	External Code Lists.....	10
<b>6</b>	<b>Validation Rules specific to the Medical Devices Context .....</b>	<b>10</b>
<b>7</b>	<b>Appendices.....</b>	<b>10</b>
<b>8</b>	<b>Summary of Changes .....</b>	<b>10</b>

# 1 Business Domain View

## 1.1 Business Need

GDSN Major Release 3.1 is contrary to previous releases based on a Modular Item approach. In previous releases all Trading Partner Neutral Information was included in one big string of classes associated with Trade Item. Extensions were created for different areas, allowing inclusion of classes specific to particular areas. (e.g. Audio Visual Photography, Chemical Ingredients, Apparel and Home Fashion, Healthcare and Food and Beverage).

Major Release 3 is the first release of GDSN having multiple specialized contexts. These contexts facilitate the assignment of reusable modules to a specific context. They have been created around specific GPC Segments, Classes and Bricks. It are these GPC elements which define the inclusion of modules into a particular context.

Context documents are not a Business Message Standard, but rather a help in identifying the constituent parts of a given context.

The context documents contain the following elements:

- A list of the GPC Segments, Classes and Bricks defining the specific Context
- A list of the modules assigned to the specific Context
- The Global Data Dictionary (GDD) reports for the included modules
- The Class Diagrams for the included modules
- The list of Validation Rules specific for the specific Context

Please refer to the GDD for detail on specific elements in the Context Documents.

## 1.2 Objective

To supply the detailed design of the (specific) business information needed to meet the requirements for Data Alignment within the context of:

- Medical Devices

## 1.3 Audience

The audience of this particular context document would be any participant in the global supply chain. This would include retailers, manufacturers, service providers and other third parties.

It is specifically intended for those participants interested in the Medical Devices Context.

## 1.4 References

Reference Name	Description
[1] BMS Shared Common Library Release 3.1	
[2] Trade Item Library Release 3.1	
[3] BRAD for Major Release GDSN 3.X	
[4] GDD ( <a href="http://apps.gs1.org/gdd">http://apps.gs1.org/gdd</a> )	

## 2 Business Context

Context Category	Value(s)
Industry	All
Geopolitical	All
Product	Medical Devices
Process	Distribute Product Information
System Capabilities	GDSN
Official Constraints	None

### 3 GPC Bricks included in the Medical Devices Context

#### 3.1 Bricks Included in Context

Segment Code	Segment Description	Family Code	Family Description	Class Code	Class Description	Brick Code	Brick Description
51000000	Healthcare	51150000	Medical Devices	51150100	Medical Devices	100005844	Medical Devices



## 4 Modules assigned to the Medical Devices Context

Module Name	Description	Link
Battery Information Module	Battery information for a trade item.	<a href="#">Battery Information Module.pdf</a>
Certification Information Module	A module containing information on certification standards to which the trade item, or the process by which it is manufactured, sourced or supplied complies	<a href="#">Certification Information Module.pdf</a>
Dangerous Substance Information Module	Details on substances that can harm people, other living organisms, property, or the environment.	<a href="#">Dangerous Substance Information Module.pdf</a>
Delivery Purchasing Information Module	A module containing information on the available ordering, purchasing and delivery for a trade item.	<a href="#">Delivery Purchasing Information Module.pdf</a>
Duty Fee Tax Information Module	A module containing information on a duty, fee or tax which may be applicable to a trade item.	<a href="#">Duty Fee Tax Information Module.pdf</a>
Healthcare Item Information Module	Information relevant to all classifications of healthcare items.	<a href="#">Healthcare Item Information Module.pdf</a>
Medical Device Trade Item Module	A module containing information on medical device trade items.	<a href="#">Medical Device Trade Item Module.pdf</a>
Packaging Information Module	Packaging information for a trade item.	<a href="#">Packaging Information Module.pdf</a>
Packaging Marking Module	A module containing details on markings on the packaging of the trade item for example dates, environment.	<a href="#">Packaging Marking Module.pdf</a>
Packaging Sustainability Module	Provides the packaging sustainability module information	<a href="#">Packaging Sustainability Module.pdf</a>
Place of Item Activity Module	Origin and other information for the purposes of customs, marketing, etc.	<a href="#">Place Of Item Activity Module.pdf</a>
Product Characteristics Module	A module used to express characteristics for a product for example values for a property such as numberOfPlays.	<a href="#">Product Characteristics Module.pdf</a>
Referenced File Detail Information Module	Information specifying a link to a file external to the message itself.	<a href="#">Referenced File Detail Information Module.pdf</a>
Regulated Trade Item Module	A module containing Information on applicable government regulations a trade item is in compliance with.	<a href="#">Regulated Trade Item Module.pdf</a>
Safety Data Sheet Module	A module containing safety data sheet or on a material safety data sheet as it is referred to in some target markets.	<a href="#">Safety Data Sheet Module.pdf</a>
Trade Item Data Carrier And Identification Module	A module used to convey any data carriers formats on the trade item and any associated GS1 application identifiers	<a href="#">Trade Item Data Carrier And Identification Module .pdf</a>
Trade Item Description Module	A module carrying general descriptions of the trade item including brand, form, variant.	<a href="#">Trade Item Description Module.pdf</a>
Trade Item Disposal Information Module	Information on the disposal of the trade item for the purposes of sustainability.	<a href="#">Trade Item Disposal Information Module .pdf</a>
Trade Item Handling Module	A module containing instructions on the way to treat goods during transport and storage.	<a href="#">Trade Item Handling Module.pdf</a>
Trade Item Lifespan Module	A module containing information on the amount of time the item	<a href="#">Trade Item Lifespan Module.pdf</a>

Module Name	Description	Link
	can or should be used, sold, etc.	
Trade Item Measurements Module	A module containing measurement information for the trade item.	<a href="#">Trade Item Measurements Module.pdf</a>
Transportation Hazardous Classification Module	A module containing information on hazardous information typically based on a specific mode of transportation as regulated by an agency for example ADR, IATA, DOT, IMDG.	<a href="#">Transportation Hazardous Classification Module.pdf</a>
Variable Trade Item Information Module	A module with information specific to variable weight or dimension trade items.	<a href="#">Variable Trade Item Information Module .pdf</a>

## 5 Enumerations and Code Lists referenced in the Medical Devices Context

### 5.1 External Code Lists

Relevant external code lists can be found at the following link:

[External Code Lists](#)

## 6 Validation Rules specific to the Medical Devices Context

Validation Rule Groupings	Link
Validations for All Product Contexts	<a href="#">GDSN Validation Rules All</a>
Validation Rules specific to the Medical Devices Context	<a href="#">GDSN Validation Rules Medical Devices R3p1p0 d3p0p0.xlsx</a>

## 7 Appendices

(Insert Content Here)

## 8 Summary of Changes

Change	Report Version	Associated WR Number
Initial draft	0.0.1	
<ul style="list-style-type: none"> <li>updated links to Trade Item modules</li> <li>updated links to Validation Rules specific to context</li> <li>updated links to external codelists</li> </ul> updated version and date of document to 0.0.2 and 30 Jan 2013	0.0.2	



Change	Report Version	Associated WR Number
<p>Updated for comment resolution of Community Review:</p> <ul style="list-style-type: none"><li>• Added line numbers to document</li><li>• Updated version to 1.0.0</li><li>• Updated all hyperlinks to point to latest version of external documents</li><li>• Removed hyperlink to VRs specific to this context as these are now in the Global VR document as well.</li><li>• Removed "Marketing Information Module"</li><li>• Removed "Non Food Ingredient Module"</li><li>• Added "Battery Information Module"</li><li>• Added " Certification Information Module"</li><li>• Added " Dangerous Substance Information Module"</li><li>• Added " Delivery Purchasing Information Module"</li><li>• Added " Duty Fee Tax Information Module"</li><li>• Added " Transportation Hazardous Classification Module"</li><li>• Added " Packaging Information Module"</li><li>• Added " Safety Data Sheet Module"</li><li>• Added " Trade Item Disposal Information Module"</li><li>• Added " Trade Item Handling Module"</li></ul> <p>Added " Trade Item Lifespan Module"</p>	1.0.0	
<p>Updated document to new format of GS1 Template</p> <p>Added in section 4: Packaging Sustainability Module, Product Characteristics Module, Variable Trade Item Information</p>	2.0	