



# Business Message Standard (BMS) GDSN Healthcare Extension

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16 June 2009	0.0.1	Brian Bennett	Initial Document Creation		
25 June 2009	0.0.2	Brian Bennett	Updates based on Group Discussions at physical Meeting	Changed Sterilisation Type list, as well as MRI Compatibility Code List	
24 Aug 2009	0.0.3	Brian Bennett	Updated per peer review comments	Updated attribute name for MRI Compatibility	
04 Nov 2009	0.0.4	Brian Bennett	Updated to add items not able to be moved into Core as part of GDSN MR4	Added Orderable Returnable Information	
8 Jan 2010	0.0.5	Brian Bennett	Fixed Case of Code List Values and Reusability class	Upper Case of all code list values	

Date of Change	Version	Changed By	Reason for Change	Summary of Change	Model Build #
8 Feb 2010	0.0.6	Brian Bennett	Typos from Public Review	Fixed typos within document from the public review.	
1 Mar 2010	0.0.7	Brian Bennett	Public Review Comments	Updated definitions for clarity and consistency	

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# 1. Business Domain View

## 1.1. Problem Statement / Business Need

Unreliable and inefficient data management in the healthcare supply chain has been shown to impact patient safety and result in increased costs for manufacturers, distributors, and Healthcare Providers. The GS1 Global Data Synchronisation Network® (GDSN) allows for the minimisation of data errors by eliminating human intervention and eliminates the need to maintain multiple catalogues. The implementation of standardised global data synchronisation through the GDSN in other sectors, particularly in the Fast Moving Consumer Goods (FMCG) sector, has proven that the infrastructure and the standards are in place, and more importantly has proven the benefits for retailers and suppliers. Also the Healthcare sector can benefit from global data synchronisation and can leverage what was established in the FMCG sector.

## 1.2. Objective

Provide an initial set of attributes needed to communicate information relating to trade items within the healthcare sector.

## 1.3. Audience

The audience of this document is those individuals implementing the Global Data Synchronisation Network (GDSN) within the Healthcare sector.

## 1.4. References

Reference Name	Description
BRAD_GDSN_Extension_Healthcare_r0_p0_p1_d0_p0_p1_09_Mar_2009.doc	GS1 GDSN Business Requirements Document
<a href="http://www.gs1.org/gsm/kc/ecom/xml/gdsn_grid">http://www.gs1.org/gsm/kc/ecom/xml/gdsn_grid</a>	GS1 Knowledge Centre: GDSN BMS Documentation Grid

## 1.5. Acknowledgements

The following is a list of individuals (and their companies) who participated in the creation, review and approval of this BMS.

### 1.5.1. BRG Work Group

Function	Name	Company / organisation
BRG Work Group Chair	Joe Pleasant	Premier
BRG Work Group Member	Tom Werthwine	J&J
BRG Work Group Member	Andersen, Ole	London Drugs Limited
BRG Work Group Member	Ausili, Mr. Andrea	GS1 Italy

Function	Name	Company / organisation
BRG Work Group Member	Bartz, Mrs. Bettina	GS1 Germany
BRG Work Group Member	Bergamin, Stefano	GS1 Italy
BRG Work Group Member	Besford, Robert	GS1 UK
BRG Work Group Member	Bisch, Francois	CHU Dijon
BRG Work Group Member	Black, Dennis	BD
BRG Work Group Member	Blaise, Nsimba	Centre Hospitalier de Nantes
BRG Work Group Member	Blanchette-Ouellet, Eric	Centre Hospitalier Universitaire de Québec (CHUQ)
BRG Work Group Member	Bledsoe, Roger	Medtronic
BRG Work Group Member	Bone, Ron*	McKesson
BRG Work Group Member	Bosson, Shaun	GS1 New Zealand
BRG Work Group Member	Bridgeford, Janine	GE Healthcare
BRG Work Group Member	Brown, Mr. Scott	GS1 US
BRG Work Group Member	Bugeja, Andrew	Medical Mart
BRG Work Group Member	Calderaro, Mr. Tony	Cardinal Health
BRG Work Group Member	Chan, Mr. Jeff	GS1 Hong Kong
BRG Work Group Member	Crowley, Jay	Food and Drug Administration (FDA)
BRG Work Group Member	Davis, Mr. Trey	Alcon Labs
BRG Work Group Member	Decieux, Mrs. Alyette	Covidien
BRG Work Group Member	Diniz, Ms. Amanda	Public Health Agency of Canada
BRG Work Group Member	Dorner, Ms. Barbara	GS1 Austria
BRG Work Group Member	Elkin, Jackie	Medtronic
BRG Work Group Member	Ference, Jackie	C. R. Bard, Inc.
BRG Work Group Member	Fitzpatrick, John	Sterling Commerce, Inc.
BRG Work Group Member	Fowler, Dawn	Edwards Lifesciences
BRG Work Group Member	Fremont, Mrs. Frederique	C.H.I Robert Ballanger
BRG Work Group Member	Frith, Mr. Cameron	GS1 New Zealand
BRG Work Group Member	Gilbert, Jean-Christopher	GS1 France
BRG Work Group Member	Gill, Mr. David	SA2 Worldsync GmbH
BRG Work Group Member	Goldman, Douglas	GS1 US
BRG Work Group Member	Gomberg, Mr. Carl	Premier Inc
BRG Work Group Member	Habeck, Nathan	Baxter Healthcare
BRG Work Group Member	Hachemi, Mr. Lyes	GS1 Algeria
BRG Work Group Member	Haehn, Michaela	GS1 Germany
BRG Work Group Member	Haggard, Mr. James	GXS (US)
BRG Work Group Member	Hanko, Ms. Christine	GS1 Hungary
BRG Work Group Member	Hansel, Mr. Leighton	Abbott Laboratories Inc.

Function	Name	Company / organisation
BRG Work Group Member	Hartley, Mr. Gary	GS1 New Zealand
BRG Work Group Member	Hay, Christian	GS1 Switzerland
BRG Work Group Member	Hee, Mr. Corwin	Covidien
BRG Work Group Member	Ho, Ms. Tina	GS1 Hong Kong
BRG Work Group Member	Hwang, Ms. Mi Jeong	GS1 Korea
BRG Work Group Member	Ichihara, Mr. Hideki	GS1 Japan
BRG Work Group Member	Jackson, Simon	Medical Standard 1
BRG Work Group Member	Joël, Gosse	CHU de Montpellier
BRG Work Group Member	Kernan, Brendan	GS1 Ireland
BRG Work Group Member	Kidd, Robin	Nestle
BRG Work Group Member	Kille, Grant	SA2 Worldsync GmbH
BRG Work Group Member	Koens, Mr. Maarten	Healthlogistics.co.uk
BRG Work Group Member	Laur, Rita	GS1 Canada
BRG Work Group Member	Luscia, Giuseppe	GS1 Italy
BRG Work Group Member	Mahdiani, Mr. Reza	GS1 Canada
BRG Work Group Member	Marchand, Valerie	GS1 France
BRG Work Group Member	Martin, Mr. Andy	GHX
BRG Work Group Member	Moelgaard, Mr. Svend Erik	Platon A/S
BRG Work Group Member	Nayir, Ibrahim	Turkish Ministry of Health, G.D. of Pharmaceuti...
BRG Work Group Member	Op den Acker, Ms. Joke	GS1 Belgium & Luxembourg
BRG Work Group Member	Parent, Cécile	CH Rene Dubos PONTOISE
BRG Work Group Member	Peelen, Mrs. Esther	GS1 Netherlands
BRG Work Group Member	Perry, Robert	Association for Healthcare Resource and Materia...
BRG Work Group Member	Peterson-Doyle, Ms. Karen	Pall Life Sciences
BRG Work Group Member	Phillips, Mr. Jack	Abbott Laboratories Inc.
BRG Work Group Member	Pimaiklang, Ms. Pimsiri	GS1 Thailand
BRG Work Group Member	Plaksin, Mr. Leon	GS1 Australia
BRG Work Group Member	Pleasant, Joe	Premier Inc
BRG Work Group Member	Poetker, Cynthia	Abbott Laboratories Inc.
BRG Work Group Member	Ramos, Mr. Carlos	GS1 Mexico
BRG Work Group Member	Recham, Halim	GS1 Algeria
BRG Work Group Member	Reed, Terrie	Food and Drug Administration (FDA)
BRG Work Group Member	Reid, David	Telus Backed by Emergis
BRG Work Group Member	Rhodes, Jim	Alberta Health Services
BRG Work Group Member	Richey, Mr. Lance	Premier Inc
BRG Work Group Member	Romac, Mr. Slobodan	GS1 Croatia

Function	Name	Company / organisation
BRG Work Group Member	Sage, Ms. Carol	Pfizer
BRG Work Group Member	Saliba, Katya	GS1 Malta
BRG Work Group Member	Schmid, Ms. Sue	GS1 Australia
BRG Work Group Member	Secunda, Jeffrey	AdvaMed
BRG Work Group Member	Sieira, Mr. Marcel	GS1 Australia
BRG Work Group Member	Smith, Mr. N Arthur	GS1 Canada
BRG Work Group Member	Snioch, Ms. Tania	GS1 Australia
BRG Work Group Member	Sobrinho, Gabriel	GS1 Netherlands
BRG Work Group Member	Soler, Ms. Monica	GS1 Spain
BRG Work Group Member	Stewart, Joanna	GXS (US)
BRG Work Group Member	Subiela, Danielle	Linde Healthcare France
BRG Work Group Member	Thakur, Mr. Lalit	Premier Inc
BRG Work Group Member	Thompson, Sue	National Council for Prescription Drug Programs
BRG Work Group Member	Tomicki, Mr. Peter	GE Healthcare
BRG Work Group Member	Tschudi, Olivier	Medical Columbus (Schweiz) AG
BRG Work Group Member	Valecha, Gopal	GS1 India
BRG Work Group Member	van Deursen, Wilbert	Medtronic
BRG Work Group Member	Ventura, Maurice	CLADIMED/VIDAL
BRG Work Group Member	Wallace, Mike	Abbott Laboratories Inc.
BRG Work Group Member	Watson, Mr. John	NHS Supply Chain
BRG Work Group Member	Wennebo, Mr. Tomas	GS1 Sweden
BRG Work Group Member	Werthwine, Mr. Thomas	Johnson & Johnson
BRG Work Group Member	Wilson, Mary	GS1 US
BRG Work Group Member	Wylie, MJ	GHX
BRG Work Group Member	Youngheim, Angela	General Dynamics For US Department of Defense
BRG Work Group Member	Zahler, Ms. Melanie	3M Company
BRG Work Group Member	Zeinar, Mr. Volker	B. Braun

### 1.5.2. Design Team Members

Function	Name	Organisation
Modeler	Brian Bennett	GS1
XML Technical Designer	Dipan Anarkat	GS1
Peer Reviewer	Eric Kauz	GS1
Process Manager	Peter Alvarez	GS1



## 2. Business Context

Context Category	Value(s)
Industry	All
Geopolitical	All
Product	All healthcare products including those classified by GPC as: 51000000 – Healthcare as well as Vaccines, Medical Devices, and Biological products (not currently listed in GPC)  As well as those products classified under the temporary GPC Codes: 9999998 9999997
Process	GDSN
System Capabilities	GS1
Official Constraints	None

## I Technical Requirements Analysis

Not Applicable

### 3.1. Technical Requirements

Not Applicable

## 4. Business Transaction View

### 4.1. Business Transaction Use Case Diagram

Not Applicable

### 4.2. Use Case Description

Not Applicable

### 4.3. Business Transaction Activity Diagram(s)

Not Applicable

### 4.4. Business Transaction Sequence Diagram(s) (optional)

Please refer to the Transaction and Sequence Diagrams listed in the GDSN Trade Item Documentation.

## 5. Information Model (Including GDD Report)

### 5.1. GDD Report

Class	Attribute	Association	Secondary Class	Definition	Multiplicity	Data Type	Facets
EnumerationValueInformation				Class containing the code list values that are maintained by an agency external to GS1			
	enumerationValue			Code List Value maintained by an external code list agency.	1..1	Text. Content	Min Length = 1; Max Length = 200
	enumerationValueDefinition			Definition of the code list value maintained by an external code list agency	0..1	Language. Identifier Language. Local Identifier Text. Content	Min Length = 1; Max Length = 1000

Class	Attribute	Association	Secondary Class	Definition	Multiplicity	Data Type	Facets
	enumerationValueDescription			Description of the value in a code list value maintained by an external code list agency. This is primarily used when code list values are sequential numbers.	0..1	Language.Identifier Language.Local.Identifier Text.Content	Min Length = 1; Max Length = 1000
ExternalCodeValueInformation				External Trade Item Code List Information			
	externalAgencyName			The name of the agency that manages a code list external to GS1.	1..1	Text.Content	Min Length = 1; Max Length = 200
	externalCodeListName			The name of the code list maintained by an agency external to GS1.	0..1	Text.Content	Min Length = 1; Max Length = 200
	externalCodeListVersion			The version of the code list maintained by an agency external to GS1.	0..1	Text.Content	Min Length = 1; Max Length = 200
			EnumerationValueInformation	This information on Enumeration Values for External Code Value Information	1..*		

Class	Attribute	Association	Secondary Class	Definition	Multiplicity	Data Type	Facets
HealthcareExtension				Base Class for the Healthcare Extension			
	doesSaleOfTradeItemRequireGovernmentalReporting			Indicates whether the government requires the reporting of sale of the trade item.	0..1	Code Content	Facets Constrained by Code List Values
	doesTradeItemContainHumanBloodDerivative			Indicates that the trade item is a product that contains blood, blood components or blood products used in the manufacturing.	0..1	Code Content	Facets Constrained by Code List Values
	doesTradeItemContainLatex			Indicates that a trade item is made from or contains latex which refers generically to a stable dispersion (emulsion) of polymer microparticles in an aqueous medium.	0..1	Code Content	Facets Constrained by Code List Values
	isTradeItemConsideredGeneric			Indicates that the trade item is being produced by someone other than the Brand Innovator of the product. A value of no indicates that it is not considered a "Generic Substitution" of another product.	0..1	Code Content	Facets Constrained by Code List Values

Class	Attribute	Association	Secondary Class	Definition	Multiplicity	Data Type	Facets
	isTradeItemConsideredDopingProduct			Indicates that the product could be considered a doping substance which is a substance which is part of the list of prohibited substances, pharmaceutical products and methods yearly published by World Anti-Doping Agency. Doping products typically fall into one of the following general types of substances: Anabolic Agents, Hormones and Related Substances, Beta-2 Agonist, Hormone Antagonist and Modulators, Diuretics and other Masking Agents, Stimulants, Narcotics, Cannabinoids, Glucocorticosteroids, Alcohol, Beta-Blockers.	0..1	Code Content	Facets Constrained by Code List Values
	isTradeItemImplantable			Indicates that the trade item is an implantable device. Implantable devices are defined as devices that are partly or totally inserted into the human body, as determined by local regulations.	0..1	Code Content	Facets Constrained by Code List Values
	mRICompatibility			Identifies the compatibility level of a trade item for use in the presence of a Magnetic Resonance Imaging (MRI) system.	0..1	Code Content	Facets Constrained by Code List Values

Class	Attribute	Association	Secondary Class	Definition	Multiplicity	Data Type	Facets
	isTradeItemMarkedNoShake			Indicates that the trade item is marked to not be shaken during transport, storage, or use.	0..1	Code Content	Facets Constrained by Code List Values
		psychotropic Substance	ExternalCodeValueInformation	<p>A psychotropic substance is any chemical agent affecting the mind or mental processes (i.e., any psychoACTIVE drug). (ii) In the context of international drug control, 'psychotropic substance' means any substance, natural or synthetic, or any natural material in Schedule I, II, III or IV of the 1971 Convention.</p> <p>*Those utilizing this functionality should be aware of the Vienna convention and requirement to annually declare stock movements to national control body. Examples of psychoactive drugs may include: amphetamines, barbiturates, and psychedelics. This class of substances includes almost any conceivable mind-altering substance.</p>	0..*		
		routeOfAdministration	ExternalCodeValueInformation	Route of Administration expresses the method(s) of administering the product. In pharmacology and toxicology, a route of administration is the path by which a drug, fluid, or other substance is brought into contact with the body.	0..*		
			HealthcareTradeItemReusabilityInformation	Information on Healthcare Trade Item Reusability for the Healthcare Extension.	0..1		

Class	Attribute	Association	Secondary Class	Definition	Multiplicity	Data Type	Facets
			Orderable Returnable Information	Information on Orderable Returnable Information for the Healthcare Extension	0..1		
			TradeItem Prescription Information	Information on Trade Item Prescription for the Healthcare Extension.	0..1		
			TradeItem Sterility Information	Information on Trade Item Sterility for the Healthcare Extension.	0..1		
HealthcareTradeItem Reusability Information				Provides the ability to specify details about the reusability of a healthcare trade item.			
	manufacturerDeclared ReusabilityType			Determines if the product is intended for single or multiple uses, including the number of validated cycles and the number of times a product can be used according to the manufacturer specifications. It is suggested that medical providers consult the device manufacturer's Instruction For Use (IFU) for full reusability instructions.	0..1	Code Content	Facets Constrained by Code List Values
	maximumCycles Reusable			Maximum number of times this Trade Item can be reused.	0..1	Numeric Content	Facets Constrained by Code List Values

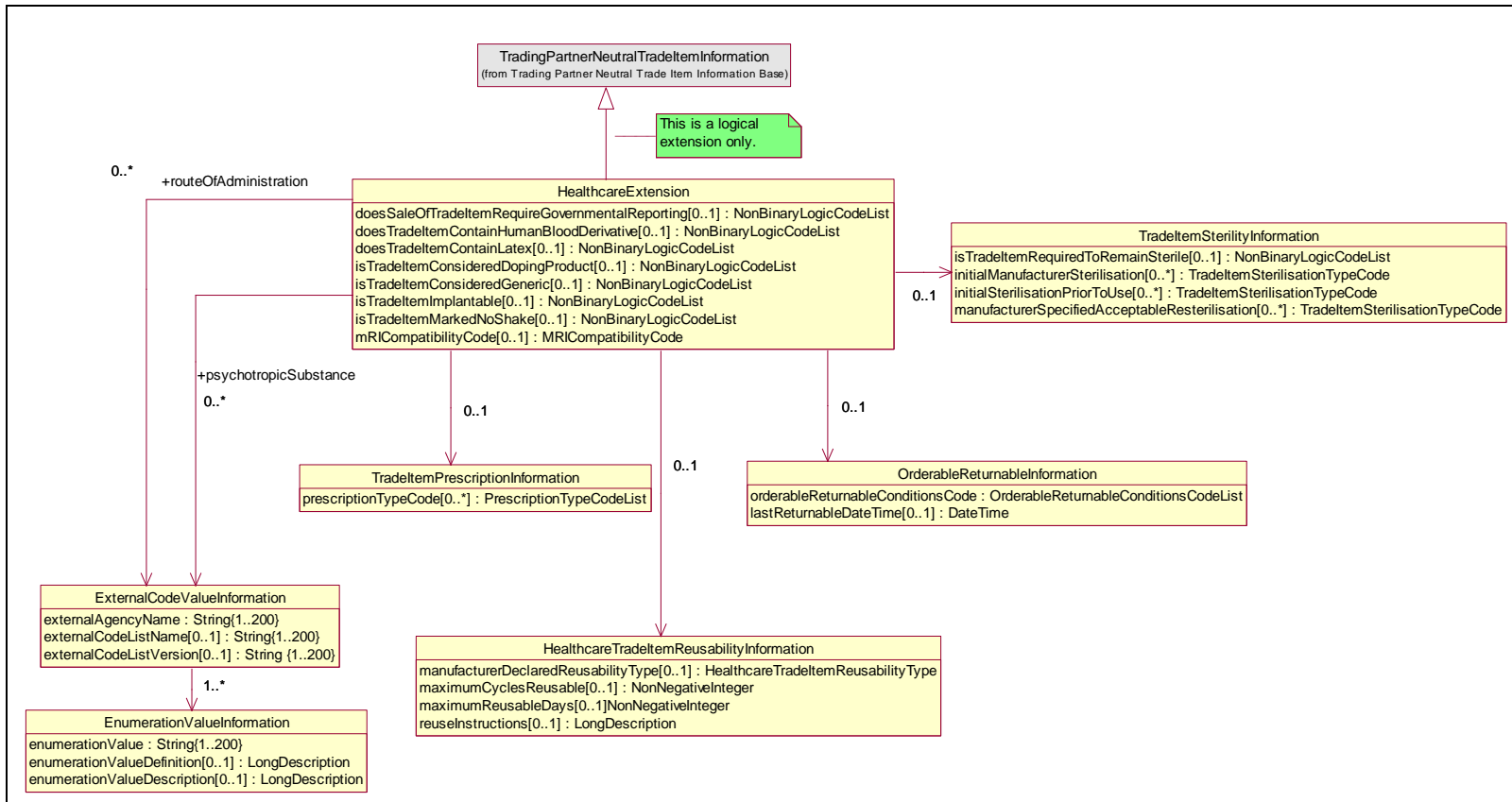
Class	Attribute	Association	Secondary Class	Definition	Multiplicity	Data Type	Facets
	maximumReusableDays			Maximum number of days this product can be reused.	0..1	Numeric. Content	Facets Constrained by Code List Values
	reuseInstructions			Additional instructions that advise the customer on the reusability limitations of this product.	0..1	Language. Identifier Language. Locale. Identifier Text. Content	Min Length : 1; Max Length : 1000;
OrderableReturnableInformation				Logical Grouping of Orderable Returnable Information			
	lastReturnableDateTime			The last date AND time when a non sold trade item must be received by the manufacturer to receive credit.	0..1	Date Time. Content Date Time. Format. Text	No restrictions



Class	Attribute	Association	Secondary Class	Definition	Multiplicity	Data Type	Facets
	orderableReturnableConditionsCode			A code that indicates if the trade item can be ordered and returned if non-sold.	1..1	Date Time. Content Date Time. Format. Text	Facets constrained by code list values
TradeItemPrescriptionInformation				Information regarding trade item prescriptions.			
	prescriptionType			Providing a value to this code list indicates the type of prescription that is required. The prescription type may indicate that it is a product that can only be prescribed under the direction of a specialist such as an oncologist, dentist, or other specialist.	0..*	Code . Content	Facets Constrained by Code List Values
TradeItemSterilityInformation				Information regarding sterility of Healthcare Trade Items.			
	initialManufacturerSterilisation			Type(s) of sterilisation that may have been performed by the manufacturer if a trade item is sterile when it comes from the manufacturer. Sterilisation refers to any process that effectively kills or eliminates transmissible agents (such as fungi, bacteria, viruses, prions and spore forms etc.) from a surface, equipment, foods, medications, or biological culture medium. Some methods of sterilisation are through the application of heat, radiation, and ethylene.	0..*	Code . Content	Facets Constrained by Code List Values

Class	Attribute	Association	Secondary Class	Definition	Multiplicity	Data Type	Facets
	initialSterilisationPriorToUse			This is an indication of the type(s) of sterilisation that is required to be completed by a healthcare provider prior to initial use of the healthcare trade item. Sterilisation refers to any process that effectively kills or eliminates transmissible agents (such as fungi, bacteria, viruses, prions and spore forms etc.) from a surface, equipment, foods, medications, or biological culture medium. Some methods of sterilisation are through the application of heat, radiation, and ethylene.	0..*	Code Content	Facets Constrained by Code List Values
	isTradeItemRequiredToRemainSterile			An indication that the products sterile status must be maintained from the point in time of sterilization until point of administration.	0..1	Code Content	Facets Constrained by Code List Values
	manufacturerSpecifiedAcceptableResterilisation			This is an list of the type(s) of acceptable sterilisation that a reusable trade item can undergo by a healthcare provider if a trade item is reusable. Sterilisation refers to any process that effectively kills or eliminates transmissible agents (such as fungi, bacteria, viruses, prions and spore forms etc.) from a surface, equipment, foods, medications, or biological culture medium. Some methods of sterilisation are through the application of heat, radiation, and ethylene.	0..*	Code Content	Facets Constrained by Code List Values

## 5.2. Class Diagrams



### 5.3. Code Lists

Code List Name	Code List Description
<b>Healthcare Trade Item Reusability Type Code List</b>	<b>Describes the manufacturer indicated reusability status of a healthcare trade item.</b>
Code Value	Code Definition
LIMITED_REUSABLE	Manufacturer has indicated that product may be reused but has provided special instructions, limitations or guidelines around the reuse of this trade item.
REUSABLE	Product can be reused
REUSABLE_SAME_PATIENT	Product can only be reused for the same patient.
SINGLE_USE	Item is not intended to be reused.

Code List Name	Code List Description
<b>MRI Compatibility Code List</b>	<b>Describes the manufacturer indicated MRI Safety level of a healthcare trade item.</b>
Code Value	Code Definition
MRI_COMPATIBLE	Indicates that a healthcare trade item is safe to use in the presence of a Magnetic Resonance Imaging (MRI) System
MRI_SAFE	Indicates that the healthcare trade item is safe to use within a Magnetic Resonance Imaging (MRI) system.
MRI_UNSAFE	Indicates that a healthcare trade item is not safe to use in an MRI system.
UNSPECIFIED	The manufacturer of the Trade Item has not communicated information on the compatibility of this trade item with a Magnetic Resonance Imaging (MRI) System.

Code List Name	Code List Description
<b>Non Binary Logic Code list</b>	<b>Not Applicable</b>
Code Value	Code Definition
FALSE	Negative value.

Code List Name	Code List Description
NOT_APPLICABLE	A statement that an affirmative or negative response is not required for the attribute.
TRUE	Affirmative value.
UNSPECIFIED	Value not stated

Code List Name	Code List Description
<b>Orderable Returnable Conditions Code List</b>	<b>Indicates if trade item can be ordered and returned if not sold.</b>
Code Value	Code Definition
ACTIVE	The trade item is an orderable unit and is returnable if not sold.
CUTOOUT	The trade item is not an orderable unit and is returnable if not sold.
DELETED	The trade item is not an orderable unit and not returnable if not sold.
HOLD	The trade item is temporarily unavailable but still returnable.

Code List Name	Code List Description
<b>Prescription Type Code List</b>	<b>Specifies the prescription type needed to for sale of trade item to a patient.</b>
Code Value	Code Definition
HOSPITAL_PRESCRIPTION	Available only through a hospital when prescribed by a doctor.
HOSPITAL_PRESCRIPTION_REQUIRED_FOR_FIRST_PRESCRIPTION	This pharmaceutical or medical device must be prescribed for the first time at a hospital.
NO_PRESCRIPTION_REQUIRED	No prescription is needed for this trade item.
PRESCRIPTION_REQUIRED_ANY_LICENSED_PRESCRIBER	A prescription is required and may be prescribed by any licensed prescriber.
SPECIALIST_PRESCRIPTION_REQUIRED	Medical Device of pharmaceutical must be prescribed under the direction of a specialist authorised to prescribe the trade item.

Code List Name	Code List Description
<b>Trade Item Sterilisation Type Code List</b>	<b>Specifies sterilisation methods that have been or are to be performed on a trade item prior to its use.</b>
Code Value	Code Definition
AUTOCLAVE	Autoclave (Steam) is a method of sterilisation that utilizes pressure and heat to achieve a sterile environment.
BETA_RADIATION	Beta particles are able to penetrate living matter to a certain extent (radiation intensity from a small source of radioactive material decreases as one over the distance squared) and can change the structure of struck molecules.
ELECTRON_BEAM_IRRADIATION	A commercially successful technology for sterilizing a variety of disposable medical devices with a wide range of densities. The e-beam inactivates micro-organisms either by causing microbial death as a direct effect of the destruction of a vital molecule or by an indirect chemical reaction. This is the same mechanism as in gamma irradiation, and the dose required is the same.
ETHANOL	A chemical sterilisation method that utilizes ethanol as the sterilisation method.
ETO_ETHYLENE_OXIDE	A gas that is commonly used to sterilize objects sensitive to temperatures greater than 60 °C such as plastics, optics and electrics. Ethylene oxide treatment is generally carried out between 30 °C and 60 °C with relative humidity above 30% and a gas concentration between 200 and 800 mg/L for at least three hours. Ethylene oxide penetrates well, moving through paper, cloth, and some plastic films and is highly effective.
FORMALDEHYDE	A chemical sterilisation agent used to provide sterilisation. Items being sterilized are usually immersed in the formaldehyde for a pre determined time period.
GAMMA_RADIATION	Gamma rays are very penetrating and are commonly used for sterilisation of disposable medical equipment, such as syringes, needles, cannulas and IV sets. Gamma radiation requires bulky shielding for the safety of the operators; they also require storage of a radioisotope (usually Cobalt-60), which continuously emits gamma rays (it cannot be turned off, and therefore always presents a hazard in the area of the facility).
GLUTERALDEHYDE	A colourless liquid with a pungent odour used to sterilize medical and dental equipment. It is also used for industrial water treatment and as a chemical preservative. Glutaraldehyde is an oily liquid at room temperature (density 1.06 g/mL), and miscible with water, alcohol, and benzene.
HYDROGEN_PEROXIDE	Another chemical sterilizing agent. It is relatively non-toxic once diluted to low concentrations (although a dangerous oxidizer at high concentrations), and leaves no residue.
OZONE	Is a method often times used in industrial settings to sterilize water and air, as well as a disinfectant for surfaces. It has the benefit of being able to oxidize most organic matter. It is a toxic and unstable gas that must be produced on-site, so it is not practical to use in many settings.
PERACETIC_ACID	A chemical in the organic peroxide family. It is a bright, colorless liquid with a characteristic acrid acetic acid type odor. It has a strong oxidizing potential, is highly corrosive, and can explode at temperatures exceeding 110 °C.
PLASMA	A method of sterilisation that utilizes hydrogen peroxide vapour to sterilize heat sensitive equipment.
UNSPECIFIED	Trade Item Manufacturer has not specified the sterilisation method(s) of the trade item.
UV_LIGHT	Useful for sterilisation of surfaces and some transparent objects. Many objects that are transparent to visible light absorb UV. UV irradiation is routinely used to sterilize the interiors of biological safety cabinets between uses.

## 6. Business Document Example

Not Applicable

## 7. Implementation Considerations

If a Healthcare Trade item is sold within the target market of Canada, and an external psychotropic code agency/value is provided, the healthcare extension should provide a “True” value within the “doesSaleOfTradeItemRequireGovernmentalReporting” attribute.

## 8. Testing

Not Applicable

### 8.1. Pass / Fail Criteria

Not Applicable

### 8.2. Test Data

Attribute	Value
prescriptionType	Hospital_Prescription
externalAgencyName	US_FDA
externalCodeListName	Route Of Administration
enumerationValue	Ocular
doesSaleOfTradeItemRequireGovernmentalReporting	False
isTradeItemMarkedNoShake	False

## 9. Appendices

Not Applicable



## 10. Summary of Changes

Change	BSD Version	Associated CR Number
Initial Document Creation	0.0.1	08-000168
Updated Document from physical meeting in Dallas	0.0.2	08-000168
Fixed minor errata	0.0.5	