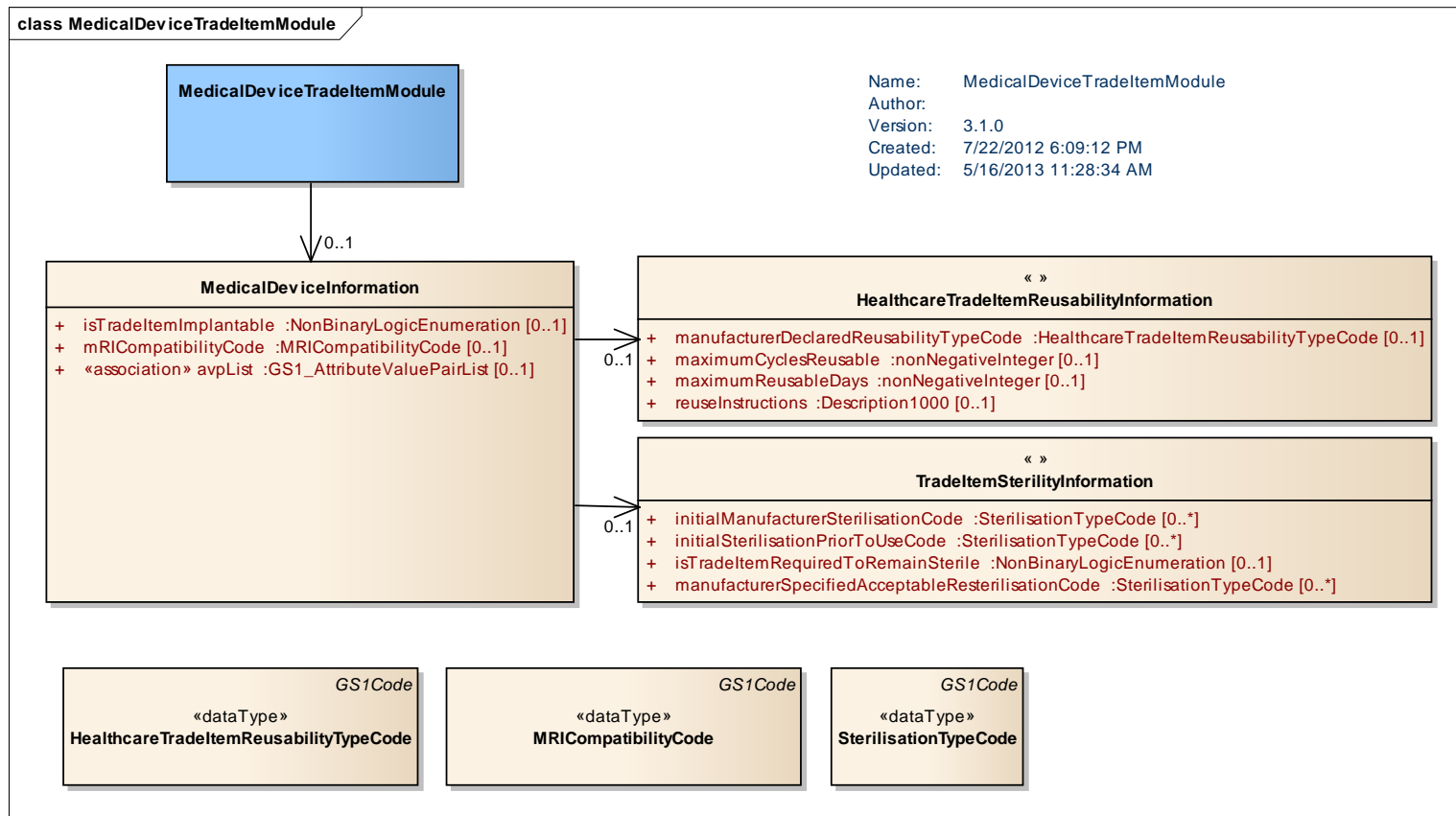


## 5.31. Medical Device Trade Item Module



content	attribute / role	datatype /secondary class	multipli city	definition
MedicalDeviceInfo rmentation				Information on medical device trade items.
Association		TradeItemSterilityIn formation	0..1	Information regarding sterility of Healthcare trade items.
Association		HealthCareTradeIt emReusabilityInfor mation	0..1	Provides the ability to specify details about the reusability of a healthcare trade item.
Association	avpList	GS1_AttributeValu ePairList	0..1	The transmission of non-standard data done in a simple, flexible, and easy to use method.
Attribute	isTradeItemImplantab le	NonBinaryLogicEn umeration	0..1	Implantable devices are defined as devices that are partly or totally inserted into the human body, as determined by local regulations.
Attribute	mRICompatibilityCod e	MRICompatibilityC ode	0..1	This is an identification of the compatibility of a trade item for use in the presence of a Magnetic Resonance Imaging (MRI) system.
MedicalDeviceInfo rmentationModule				A module containing information on medical device trade items.
Association		MedicalDeviceInfor mation	0..1	Information on medical device trade items.
HealthcareTradeIt emReusabilityInfor mation				Provides the ability to specify details about the reusability of a healthcare trade item.
Attribute	manufacturerDeclare dReusabilityTypeCod e	HealthcareTradeIt emReusabilityTypeC ode	0..1	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.
Attribute	maximumCyclesReus able	nonNegativeIntege r	0..1	Maximum number of times this Trade Item can be reused.
Attribute	maximumReusableD ays	nonNegativeIntege r	0..1	Maximum number of days this product can be reused.
Attribute	reuseInstructions	Description1000	0..1	Additional instructions that advise the customer on the reusability limitations of this product.
TradeItemSterilityI nformation				Information regarding sterility of Healthcare trade items.

content	attribute / role	datatype /secondary class	multipli city	definition
Attribute	initialManufacturerSterilisationCode	SterilisationTypeCode	0..*	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.
Attribute	initialSterilisationPriorToUseCode	SterilisationTypeCode	0..*	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.
Attribute	isTradeItemRequiredToRemainSterile	NonBinaryLogicEnumeration	0..1	An indication that the products sterile status must be maintained from the point in time of sterilisation until point of administration.
Attribute	manufacturerSpecifiedAcceptableResterilisationCode	SterilisationTypeCode	0..*	This is a 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.