

# Health & Care Information Model: nl.zorg.MedicalDevice-v3.1.1

Status:Final

Release:2018

Release status: Prepublished

Managed by:



# Content

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# 1. nl.zorg.MedicalDevice-v3.1.1

DCM::CoderList	Kerngroep Registratie aan de Bron
DCM::ContactInformation.Address	*
DCM::ContactInformation.Name	*
DCM::ContactInformation.Telecom	*
DCM::ContentAuthorList	Projectgroep Generieke Overdrachtsgegevens & Kerngroep Registratie aan de Bron
DCM::CreationDate	2-1-2013
DCM::DeprecatedDate	
DCM::DescriptionLanguage	nl
DCM::EndorsingAuthority.Address	
DCM::EndorsingAuthority.Name	PM
DCM::EndorsingAuthority.Telecom	
DCM::Id	2.16.840.1.113883.2.4.3.11.60.40.3.10.1
DCM::KeywordList	medisch hulpmiddel, implantaat
DCM::LifecycleStatus	Final
DCM::ModelerList	Kerngroep Registratie aan de Bron
DCM::Name	nl.zorg.MedischHulpmiddel
DCM::PublicationDate	01-10-2018
DCM::PublicationStatus	Prepublished
DCM::ReviewerList	Projectgroep Generieke Overdrachtsgegevens & Kerngroep Registratie aan de Bron
DCM::RevisionDate	31-12-2017
DCM::Superseeds	nl.zorg.MedischHulpmiddel-v3.1
DCM::Version	3.1.1
HCIM::PublicationLanguage	EN

## 1.1 Revision History

Publicatieversie 1.0 (15-02-2013)

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Publicatieversie 1.1 (01-07-2013)

Bevat: ZIB-11.

Publicatieversie 1.2 (01-04-2015)

Bevat: ZIB-83, ZIB-88, ZIB-110, ZIB-249, ZIB-250, ZIB-251, ZIB-252, ZIB-308, ZIB-327, ZIB-353.

Incl. algemene wijzigingsverzoeken:

ZIB-94, ZIB-154, ZIB-200, ZIB-201, ZIB-309, ZIB-324, ZIB-326.

Publicatieversie 3.0 (01-05-2016)

Bevat: ZIB-453

Publicatieversie 3.1 (04-09-2017)

Bevat: ZIB-457, ZIB-461, ZIB-517, ZIB-522, ZIB-547, ZIB-549, ZIB-564,. ZIB-568, ZIB-573, ZIB-574, ZIB-578, ZIB-585.

Publicatieversie 3.1.1 (01-10-2018)

Bevat: ZIB-673.

## 1.2 Concept

Medical devices are any internally implanted and external devices and/or aids used by the patient (in the past) to reduce the effects of functional limitations in organ systems or to facilitate the treatment of a disease.

### 1.3 Purpose

Data on medical devices is recorded for several reasons. Knowledge of the presence of these implants enables tracing and taking the aid or device into account in diagnostic or therapeutic procedures, care and transport.

Examples include:

- Consequences for transportation, toilet use, etc., in the case of a wheelchair;
- A pacemaker can be of medical importance, but also has consequences for planning radiological exams.

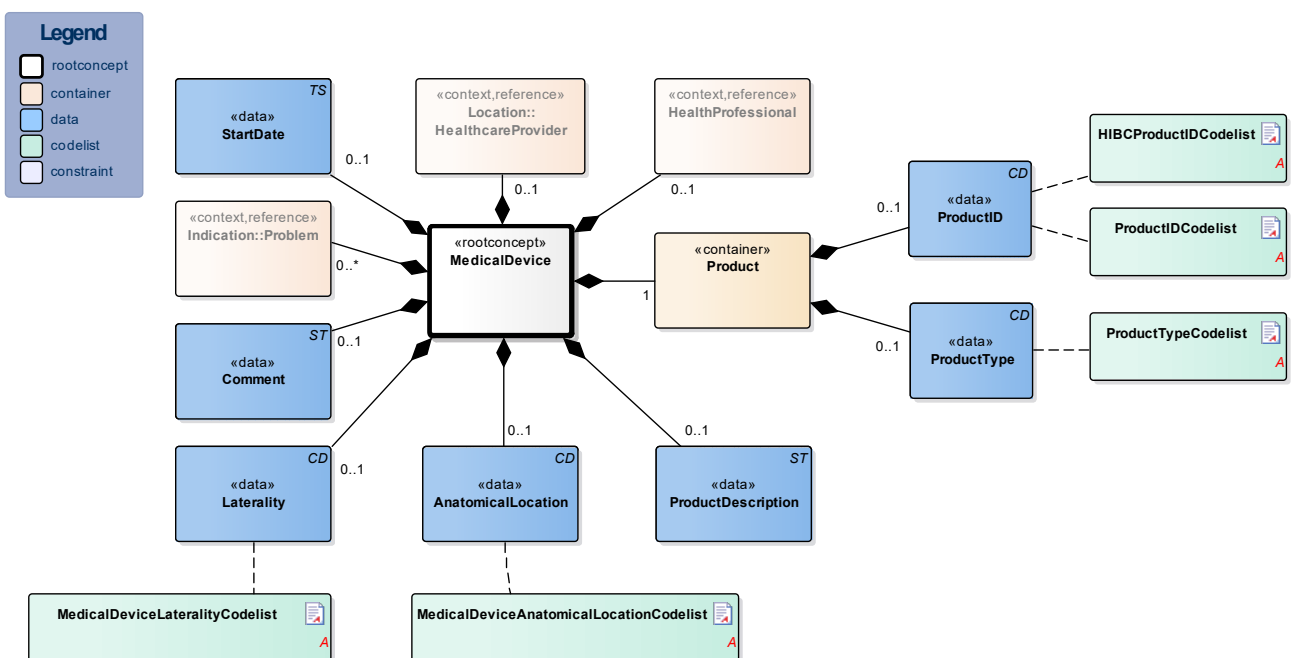
### 1.4 Patient Population

### 1.5 Evidence Base

Recording data on medically complex devices such as pacemakers is not yet common in EPD systems in the Netherlands, but is sometimes lacking: a letter from a specialist for example often does not include information on which type of pacemaker the patient has (and from which manufacturer).

The Dutch Ministry of Health, Welfare and Sport (VWS) will pass legislation for a national basic register of implants. Every healthcare center will have to supply a UDI (Unique Device Identification, with a link to GTIN) and a UPI (Unique Patient Identification) to the basic register. This will prevent situations in which a large group of patients have an aid or implant in which problems have been detected that cannot be traced.

### 1.6 Information Model



<b>Definitie</b>	Root concept of the MedicalDevice information model. This root concept contains all data elements of the MedicalDevice information model.	
<b>Datatype</b>		
<b>DCM::ConceptId</b>	NL-CM:10.1.1	
<b>DCM::DefinitionCode</b>	SNOMED CT: 49062001 Device (physical object)	
<b>Opties</b>		

<b>«container»</b>	<b>Product</b>	
<b>Definitie</b>	The medical device (internally or externally).	
<b>Datatype</b>		
<b>DCM::ConceptId</b>	NL-CM:10.1.2	
<b>DCM::DefinitionCode</b>	SNOMED CT: 405815000 Procedure device	
<b>Opties</b>		

<b>«data»</b>	<b>ProductID</b>	
<b>Definitie</b>	<p>Unique identification of the product, such as the serial number. Frequently used coding systems are HIBC and GTIN. If the law requires this to be registered on the basis of a UDI (Unique Device Identifier), the unique identification must consist of a UDI-DI (Device Identifier) and a UDI-PI (Production Identifier(s)). See <a href="http://www.gs1.org/healthcare/udi">http://www.gs1.org/healthcare/udi</a> for more information.</p> <p>The UDI-DI must be recorded in reference to GS1 GTIN (01) encryptions, with which for example a firm is linked to the product type. The UDI-PI must consist of the following: application identifier (AI); expiration date (17) and serial number (21) and/or batch or lot number (10).</p>	
<b>Datatype</b>	CD	
<b>DCM::ConceptId</b>	NL-CM:10.1.4	
<b>DCM::ExampleValue</b>	(01)08712345000004(17)160 131(10)200652	
<b>DCM::ValueSet</b>	HIBCProductIDCodelist	OID: 2.16.840.1.113883.2.4.3.11.60.40.2.10.1.5
<b>DCM::ValueSet</b>	ProductIDCodelist	OID: 2.16.840.1.113883.2.4.3.11.60.40.2.10.1.3
<b>Opties</b>		

<b>«data»</b>	<b>ProductType</b>	
<b>Definitie</b>	The code of the type of product.	
<b>Datatype</b>	CD	
<b>DCM::ConceptId</b>	NL-CM:10.1.3	
<b>DCM::ExampleValue</b>	58938008 Wheelchair	
<b>DCM::ValueSet</b>	ProductTypeCodelist	OID: 2.16.840.1.113883.2.4.3.11.60.40.2.10.1.1
<b>Opties</b>		

<b>«data»</b>	<b>ProductDescription</b>	
<b>Definitie</b>	Textual description of the product.	
<b>Datatype</b>	ST	

<b>DCM::ConceptId</b>	NL-CM:10.1.13	
<b>Opties</b>		

<b>«data»</b>	<b>StartDate</b>	
<b>Definitie</b>	The start date of the first use or implant of the medical device. A 'vague' date, such as only the year, is permitted.	
<b>Datatype</b>	TS	
<b>DCM::ConceptId</b>	NL-CM:10.1.11	
<b>DCM::ExampleValue</b>	24-02-2003	
<b>Opties</b>		

<b>«context»</b>	<b>Indication::Problem</b>	
<b>Definitie</b>	The medical reason for use of the medical device.	
<b>Datatype</b>		
<b>DCM::ConceptId</b>	NL-CM:10.1.7	
<b>DCM::ExampleValue</b>	presbycusis (ICD10::H91.1)	
<b>DCM::ReferencedConceptId</b>	NL-CM:5.1.1	This is a reference to the rootconcept of information model Problem.
<b>Opties</b>		

<b>«data»</b>	<b>Comment</b>	
<b>Definitie</b>	Comment about use or information on the medical device used.	
<b>Datatype</b>	ST	
<b>DCM::ConceptId</b>	NL-CM:10.1.10	
<b>DCM::DefinitionCode</b>	LOINC: 48767-8 Annotation comment	
<b>Opties</b>		

<b>«data»</b>	<b>AnatomicalLocation</b>	
<b>Definitie</b>	Patient's anatomical location of the medical device used.	
<b>Datatype</b>	CD	
<b>DCM::ConceptId</b>	NL-CM:10.1.6	
<b>DCM::DefinitionCode</b>	SNOMED CT: 363698007 Finding site	
<b>DCM::ExampleValue</b>	Oor	
<b>DCM::ValueSet</b>	MedicalDeviceAnatomicalLocationCodeList	OID: 2.16.840.1.113883.2.4.3.11.60.40.2.10.1.2
<b>Opties</b>		

<b>«data»</b>	<b>Laterality</b>	
<b>Definitie</b>	Laterality adds information about body side to the anatomic location, <i>e.g.</i> left	
<b>Datatype</b>	CD	
<b>DCM::ConceptId</b>	NL-CM:10.1.12	
<b>DCM::DefinitionCode</b>	SNOMED CT: 272741003 Laterality	
<b>DCM::ExampleValue</b>	Links	
<b>DCM::ValueSet</b>	MedicalDeviceLateralityCodeList	OID: 2.16.840.1.113883.2.4.3.11.60.40.2.10.1.4
<b>Opties</b>		

«context»		Location::HealthcareProvider	
Definitie	The healthcare provider at which use of the medical device was initiated or where the aid was implanted.		
Datatype			
DCM::ConceptId	NL-CM:10.1.8		
DCM::ReferencedConceptId	NL-CM:17.2.1	This is a reference to the rootconcept of information model HealthcareProvider	
Opties			

«context»		HealthProfessional	
Definitie	The healthcare provider involved in the indication for use of the medical device implant.		
Datatype			
DCM::ConceptId	NL-CM:10.1.9		
DCM::ReferencedConceptId	NL-CM:17.1.1	This is a reference to rootconcept of information model HealthProfessional	
Opties			

«document»		HIBCProductIDCodelist	
Definitie			
Datatype			
DCM::ValueSetBinding	Extensible		
DCM::ValueSetId	2.16.840.1.113883.2.4.3.11.60.40.2.10.1.5		
Opties			
<b>HIBCProductIDCodelijst</b>		<b>OID: 2.16.840.1.113883.2.4.3.11.60.40.2.10.1.5</b>	
Codes	Coding Syst. Name	Coding System OID	
Alle waarden	Health Industry Bar Code (HIBC)	2.16.840.1.113883.6.40	

«document»		MedicalDeviceAnatomicalLocationCodelist	
Definitie			
Datatype			
DCM::ValueSetBinding	Extensible		
DCM::ValueSetId	2.16.840.1.113883.2.4.3.11.60.40.2.10.1.2		
Opties			
<b>HulpmiddelAnatomischeLocatieCodelijst</b>		<b>OID: 2.16.840.1.113883.2.4.3.11.60.40.2.10.1.2</b>	
Codes	Coding Syst. Name	Coding System OID	
SNOMED CT: < 442083009  Anatomical or acquired body structure	SNOMED CT	2.16.840.1.113883.6.96	

«document»		MedicalDeviceLateralityCodelist	
Definitie			
Datatype			
DCM::ValueSetBinding	Extensible		

<b>DCM::ValueSetId</b>	2.16.840.1.113883.2.4.3.11.60.40.2.10.1.4			
<b>Opties</b>				
<b>MedischHulpmiddelLateraliteitCodelijst</b>		<b>OID: 2.16.840.1.113883.2.4.3.11.60.40.2.10.1.4</b>		
<b>Concept Name</b>	<b>Concept Code</b>	<b>CodeSys. Name</b>	<b>CodeSystem OID</b>	<b>Description</b>
Left	7771000	SNOMED CT	2.16.840.1.113883.6.96	Links
Right	24028007	SNOMED CT	2.16.840.1.113883.6.96	Rechts
Right and left	51440002	SNOMED CT	2.16.840.1.113883.6.96	Rechts en links

<b>«document»</b>	<b>ProductIDCodelist</b>		
<b>Definitie</b>			
<b>Datatype</b>			
<b>DCM::ValueSetBinding</b>	Extensible		
<b>DCM::ValueSetId</b>	2.16.840.1.113883.2.4.3.11.60.40.2.10.1.3		
<b>Opties</b>			
<b>GTINProductIDCodelijst</b>		<b>OID: 2.16.840.1.113883.2.4.3.11.60.40.2.10.1.3</b>	
<b>Codes</b>	<b>Coding Syst. Name</b>	<b>Coding System OID</b>	
Alle waarden	Global Trade Item Number (GTIN)	1.3.160	

<b>«document»</b>	<b>ProductTypeCodelist</b>		
<b>Definitie</b>			
<b>Datatype</b>			
<b>DCM::ValueSetBinding</b>	Extensible		
<b>DCM::ValueSetId</b>	2.16.840.1.113883.2.4.3.11.60.40.2.10.1.1		
<b>Opties</b>			
<b>ProductTypeCodelijst</b>		<b>OID: 2.16.840.1.113883.2.4.3.11.60.40.2.10.1.1</b>	
<b>Codes</b>	<b>Coding Syst. Name</b>	<b>Coding System OID</b>	
Alle waarden	SNOMED CT	2.16.840.1.113883.6.96	

## 1.7 Example Instances



Begin Datum	Product		Anatomische Locatie	Lateraliteit	Indicatie	Locatie		Toelichting
	ProductID	ProductType			ProbleemNaam	Organisatie Naam	Afdeling Specialisme	
08-03-2012	GTIN/HIBC code	Rolstoel			Multiple sclerose			Kan korte afstanden lopen

Begin Datum	Product		Anatomische Locatie	Lateraliteit	Lateraliteit	Locatie		Toelichting
	ProductID	ProductType			ProbleemNaam	Organisatie Naam	Afdeling Specialisme	
2007	GTIN/HIBC code	Gehoorapparaat	Oor	Rechts	Presbycusis	St. Franciscus Gasthuis	Audiologie	Apparaat niet zichtbaar (diep in de gehooringang)

Begin Datum	Product		Anatomische Locatie	Lateraliteit	Indicatie	Locatie		Toelichting
	ProductID	ProductType			ProbleemNaam	Organisatie Naam	Afdeling Specialisme	
10-02-2004	GTIN/HIBC code	Pacemaker	Subclavian pouch	Links	Paroxymaal boezemfibrilleren	Academisch Medisch Centrum	Cardiologie	Laatst doorgemeten in 2011

## 1.8 Instructions

## 1.9 Interpretation

## 1.10 Care Process

## 1.11 Example of the Instrument

## 1.12 Constraints

## 1.13 Issues

The UNSPSC code system has a great many products (including non-medical products). That is why a Dutch set and/or subcollection of this code system is required to indicate the type of product. We have currently opted to consider all values in the UNSPSC for documenting the type of medical device product in the absence of such a set.

## 1.14 References

1. Kamerbrief over het voorstel voor een register van implantaten. [Online] Beschikbaar op: <http://www.rijksoverheid.nl/documenten-en-publicaties/kamerstukken/2012/11/20/kamerbrief-over-het-voorstel-voor-een-register-van-implantaten.html> [Geraadpleegd: 15 september 2014].

## 1.15 Functional Model

## 1.16 Traceability to other Standards

## 1.17 Disclaimer

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