

# **Health & Care Information Model:**

## **nl.zorg.MedicalDevice-v4.0**

Status: Final

Release status: Prepublished

# Content

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# 1. nl.zorg.MedicalDevice-v4.0

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
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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
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DCM::Version	4.0
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.

Publicatieversie 3.2 (26-02-2019)

Bevat: ZIB-680.

Publicatieversie 3.3 (06-07-2019)

Bevat: ZIB-734.

Publicatieversie 3.3.1 (01-09-2020)  
Bevat: ZIB-1116, ZIB-1135, ZIB-1120.

Publicatieversie 3.4 (01-12-2021)  
Bevat: ZIB-1279, ZIB-1534.

Publicatieversie 3.5 (10-06-2022)  
Bevat: ZIB-1535.

Publicatieversie 4.0 (15-10-2023)  
Bevat: ZIB-1536, ZIB-1778, ZIB-1974.

## 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:

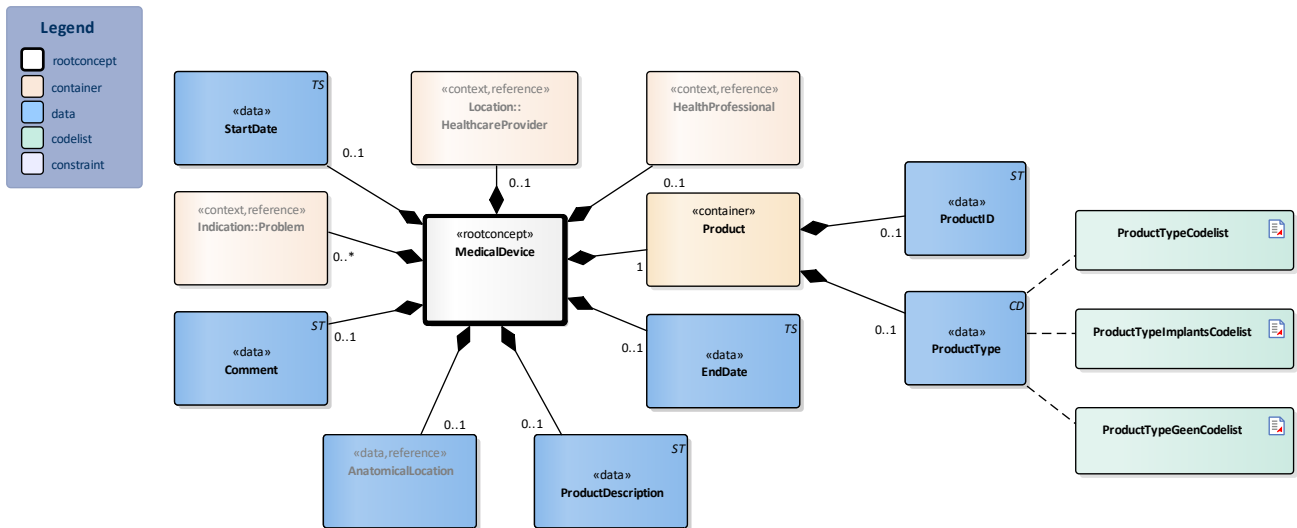
- Consequences for transportation, toilet use, etc., in the case of a wheelchair;
- A pacemaker can be of medical importance, but also has consequences for planning radiological exams.

## 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



«rootconcept»	MedicalDevice
<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>	

«container»	Product
<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>	

«data»	ProductType
<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>	ProductTypeGeenCodelist OID: 2.16.840.1.113883.2.4.3.11.60.40.2.10.1.7
<b>DCM::ValueSet</b>	ProductTypeCodelist OID: 2.16.840.1.113883.2.4.3.11.60.40.2.10.1.1
<b>DCM::ValueSet</b>	ProductTypeImplantsCodelist OID: 2.16.840.1.113883.2.4.3.11.60.40.2.10.1.6
<b>Opties</b>	

«data»	ProductID
<b>Definitie</b>	Globally unique identification of the product, for example the serial number or a UDI (unique device identifier). For some products, the law requires the use of a UDI. Commonly used coding systems are HIBC and GS1/GTIN.  A UDI often contains more information than just an ID, but also, for example, an expiration date. If a UDI is used, the entire code can be included as text in ProductID, so that no important information is lost.

<b>Datatype</b>	ST	
<b>DCM::ConceptId</b>	NL-CM:10.1.16	
<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>AnatomicalLocation</b>	
<b>Definitie</b>	Patient's anatomical location of the medical device used.	
<b>Datatype</b>		
<b>DCM::ConceptId</b>	NL-CM:10.1.15	
<b>DCM::DefinitionCode</b>	SNOMED CT: 363698007 Finding site	
<b>DCM::ExampleValue</b>	Rechter oor	
<b>DCM::ReferencedConceptId</b>	NL-CM:20.7.1	This is a reference to the rootconcept of information model AnatomicalLocation.
<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>	presbyacusic (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>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>«data»</b>	<b>EndDate</b>	
<b>Definitie</b>	The end date of the last use or explant of the medical device. A 'vague' date, such as only the year, is permitted.	
<b>Datatype</b>	TS	
<b>DCM::ConceptId</b>	NL-CM:10.1.14	
<b>DCM::ExampleValue</b>	26-03-2008	
<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>		

«context»	Location::HealthcareProvider	
Definitie	The healthcare provider where 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 health professional 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»	ProductTypeGeenCodelist			
Definitie	Intended to be used with VisualFunction and HearingFunction.			
Datatype				
DCM::ValueSetBinding	Required			
DCM::ValueSetId	2.16.840.1.113883.2.4.3.11.6 0.40.2.10.1.7			
HCIM::ValueSetLanguage	NL			
Opties				
ProductTypeGeenCodelijst			OID: 2.16.840.1.113883.2.4.3.11.60.40.2.10.1.7	
Concept Name	Concept Code	Coding Syst. Name	Coding System OID	Description
Geen	0	Hulpmiddelen gehoor	2.16.840.1.113883.2.4.3.11.22.211	geen gehoorapparaat
Geen	0	eCare codes	2.16.840.1.113883.2.4.3.11.22.218	geen visuele hulpmiddelen

«document»	ProductTypeImplantsCodelist		
Definitie			
Datatype			
DCM::ValueSetBinding	Required		
DCM::ValueSetId	2.16.840.1.113883.2.4.3.11.6 0.40.2.10.1.6		
HCIM::ValueSetLanguage	--		
Opties			
ProductTypeImplantatenCodelijst		OID: 2.16.840.1.113883.2.4.3.11.60.40.2.10.1.6	
Codes	Coding Syst. Name	Coding System OID	
SNOMED CT: ^52801000146101   Dutch implant registry simple reference set	SNOMED CT	2.16.840.1.113883.6.96	

«document»	ProductTypeCodelist	
Definitie		
Datatype		
DCM::ValueSetBinding	Required	

<b>DCM::ValueSetId</b>	2.16.840.1.113883.2.4.3.11.6 0.40.2.10.1.1	
<b>HCIM::ValueSetLanguage</b>	--	
<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>
SNOMED CT: < 260787004   physical object	SNOMED CT	2.16.840.1.113883.6.96

Legend	
<b>Definitie</b>	
<b>Datatype</b>	
<b>Opties</b>	

## 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

## 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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