

Health & Care Information Model:

nl.zorg.MedicalDevice-v3.4

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1. nl.zorg.MedicalDevice-v3.4

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	01-12-2021
DCM::PublicationStatus	Prepublished
DCM::ReviewerList	Projectgroep Generieke Overdrachtsgegevens & Kerngroep Registratie aan de Bron
DCM::RevisionDate	27-09-2021
DCM::Supersedes	nl.zorg.MedischHulpmiddel-v3.3.1
DCM::Version	3.4
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.

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.

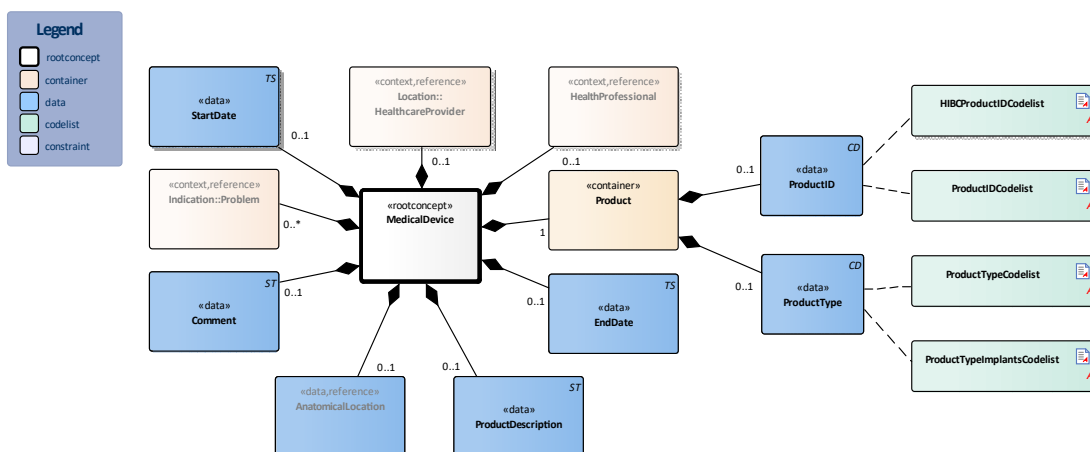
1.4 Patient Population

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

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

«data»	ProductID	
Definitie	<p>Unique identification of the product, such as the serial number. Frequently used coding systems are HIBC and GTIN.</p> <p>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 http://www.gs1.org/healthcare/udi 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 (A1); expiration date (17) and serial number (21) and/or batch or lot number (10).</p>	
Datatype		
DCM::ConceptId	NL-CM:10.1.4	
DCM::ExampleValue	(01)08712345000004(17)160131(10)200652	
DCM::ValueSet	HIBCProductIDCodelist	OID: 2.16.840.1.113883.2.4.3.11.60.40.2.10.1.5
DCM::ValueSet	ProductIDCodelist	OID: 2.16.840.1.113883.2.4.3.11.60.40.2.10.1.3
Opties		

«data»	ProductType	
Definitie	The code of the type of product.	
Datatype		
DCM::ConceptId	NL-CM:10.1.3	
DCM::ExampleValue	58938008 Wheelchair	
DCM::ValueSet	ProductTypeCodelist	OID: 2.16.840.1.113883.2.4.3.11.60.40.2.10.1.1
DCM::ValueSet	ProductTypeImplantsCodelist	OID: 2.16.840.1.113883.2.4.3.11.60.40.2.10.1.6
Opties		

«data»	ProductDescription	
Definitie	Textual description of the product.	
Datatype		
DCM::ConceptId	NL-CM:10.1.13	

Opties	
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«data»	AnatomicalLocation	
Definitie	Patient's anatomical location of the medical device used.	
Datatype		
DCM::ConceptId	NL-CM:10.1.15	
DCM::DefinitionCode	SNOMED CT: 363698007	
	Finding site	
DCM::ExampleValue	Rechter oor	
DCM::ReferencedConceptId	NL-CM:20.7.1	This is a reference to the rootconcept of information model AnatomicalLocation.
Opties		

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

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

«data»	EndDate	
Definitie	The end date of the last use or explant of the medical device. A 'vague' date, such as only the year, is permitted.	
Datatype		
DCM::ConceptId	NL-CM:10.1.14	
DCM::ExampleValue	26-03-2008	
Opties		

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

«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»	ProductTypeImplantsCodelist	
Definitie		
Datatype		
DCM::ValueSetBinding	Required	
DCM::ValueSetId	2.16.840.1.113883.2.4.3.11.60.40.2.10.1.6	
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»	HIBCProductIDCodelist	
Definitie		
Datatype		
DCM::ValueSetBinding	Required	
DCM::ValueSetId	2.16.840.1.113883.2.4.3.11.60.40.2.10.1.5	
HCIM::ValueSetLanguage	--	
Opties		

HIBCProductIDCodelijst **OID: 2.16.840.1.113883.2.4.3.11.60.40.2.10.1.5**

Codes	Coding Syst. Name	Coding System OID
Alle waarden	Health Industry Bar Code (HIBC)	2.16.840.1.113883.6.40

«document»	ProductIDCodelist	
Definitie		
Datatype		
DCM::ValueSetBinding	Required	
DCM::ValueSetId	2.16.840.1.113883.2.4.3.11.60.40.2.10.1.3	
HCIM::ValueSetLanguage	--	
Opties		

GTINProductIDCodelijst **OID: 2.16.840.1.113883.2.4.3.11.60.40.2.10.1.3**

Codes	Coding Syst. Name	Coding System OID
Alle waarden	Global Trade Item Number (GTIN)	1.3.160

«document»		ProductTypeCodelist	
Definitie			
Datatype			
DCM::ValueSetBinding	Required		
DCM::ValueSetId	2.16.840.1.113883.2.4.3.11.60.40.2.10.1.1		
HCIM::ValueSetLanguage	--		
Opties			
ProductTypeCodelijst		OID: 2.16.840.1.113883.2.4.3.11.60.40.2.10.1.1	
Codes	Coding Syst. Name	Coding System OID	
SNOMED CT: < 260787004 physical object	SNOMED CT	2.16.840.1.113883.6.96	

Legend	
Definitie	
Datatype	
Opties	

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	Lateraleit	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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