

Health & Care Information Model:

nl.zorg.MedicalDevice-v4.0

Status: Final

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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
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	15-10-2023
DCM::PublicationStatus	Prepublished
DCM::ReviewerList	Projectgroep Generieke Overdrachtsgegevens & Kerngroep Registratie aan de Bron
DCM::RevisionDate	17-07-2023
DCM::Supersedes	nl.zorg.MedischHulpmiddel-v3.5
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.

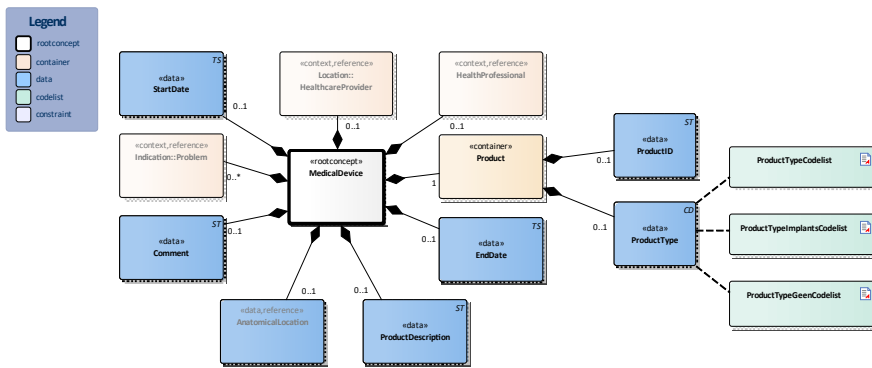
1.4 Patient Population

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
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»	ProductType
Definitie	The code of the type of product.
Datatype	CD
DCM::ConceptId	NL-CM:10.1.3
DCM::ExampleValue	58938008 Wheelchair
DCM::ValueSet	ProductTypeGeenCodeList OID: 2.16.840.1.113883.2.4.3.11.60.40.2.10.1.7
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»	ProductID
Definitie	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.

Datatype	ST	
DCM::ConceptId	NL-CM:10.1.16	
Opties		

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

«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	TS	
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	TS	
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	ST	
DCM::ConceptId	NL-CM:10.1.10	
DCM::DefinitionCode	LOINC: 48767-8	Annotation comment
Opties		

«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	2.16.840.1.113883.2.4.3.11.60.40.2.10.1.7	
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	2.16.840.1.113883.2.4.3.11.60.40.2.10.1.6	
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»	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	Indicatie	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

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