# Health & Care Information Model:

# nl.zorg.MedicalDevice-v3.0

Status:Final
Release:2016
Release status: Published

Managed by:

Better health
through better IT

Nictiz

# Content

# 1. nl.zorg.MedicalDevice-v3.0

| | |
|---|---|
| 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 | 1-5-2016 |
| DCM::PublicationStatus | Published |
| DCM::ReviewerList | Projectgroep Generieke Overdrachtsgegevens & Kerngroep Registratie aan de Bron |
| DCM::RevisionDate | 1-4-2015 |
| DCM::Superseeds | nl.nfu.MedischHulpmiddel-v1.2 |
| DCM::Version | 3.0 |
| HCIM::PublicationLanguage | EN |

## 1.1 Revision History

Publicatieversie 1.0 (15-02-2013)
-

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

## 1.2 Concept

Medical aids 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 aids 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

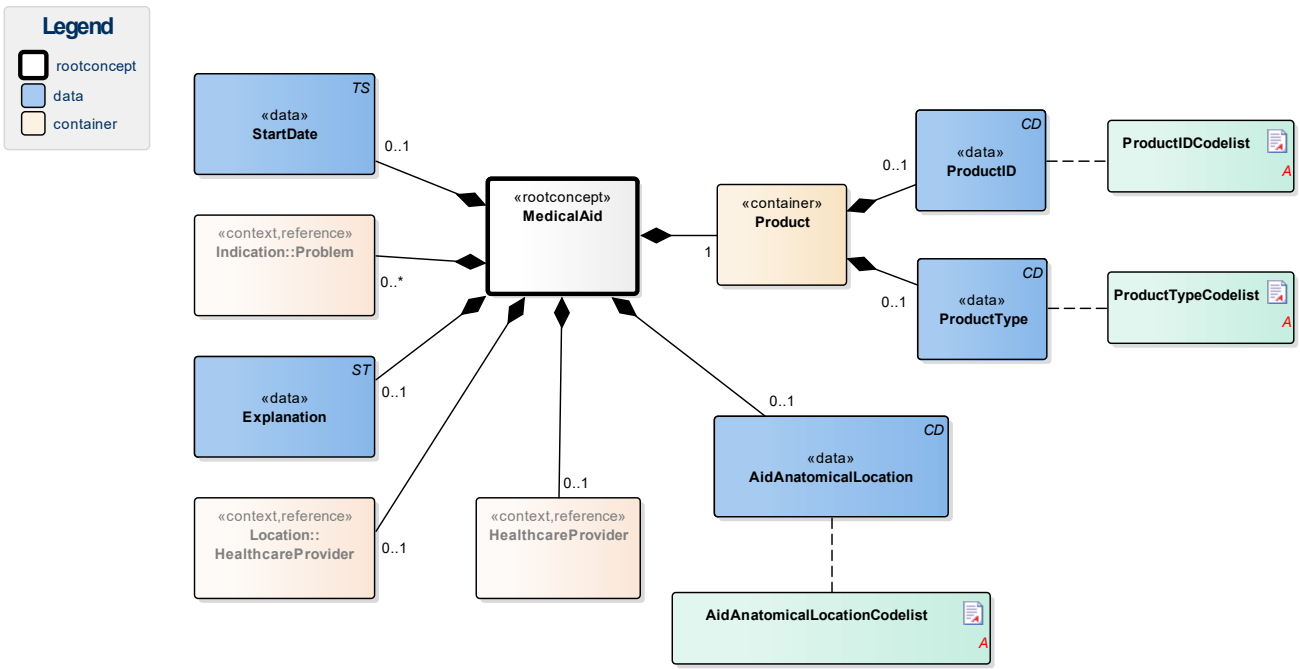
## 1.5 Evidence Base

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 NFU opts for GS1 standards to increase patient safety and improve logistic efficiency.

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» | MedicalAid | |
|---|---|---|
| **Definitie** | Root concept of the MedicalAid information model. This root concept contains all data elements of the MedicalAid information model. | |
| **Datatype** | | |
| **DCM::ConceptId** | NL-CM:10.1.1 | |
| **Opties** | | |

| «container» | Product | |
|---|---|---|
| **Definitie** | The medical aid used (internally or externally). | |
| **Datatype** | | |
| **DCM::ConceptId** | NL-CM:10.1.2 | |
| **Opties** | | |

| «data» | ProductID | |
|---|---|---|
| **Definitie** | Unique identification of the product, such as the serial number.<br><br>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.<br><br>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). | |
| **Datatype** | CD | |
| **DCM::ConceptId** | NL-CM:10.1.4 | |
| **DCM::ExampleValue** | (01)08712345000004(17)160131(10)200652 | |
| **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** | CD | |
| **DCM::ConceptId** | NL-CM:10.1.3 | |
| **DCM::ExampleValue** | 42192210 Wheelchairs | |
| **DCM::ValueSet** | ProductTypeCodelist | OID: 2.16.840.1.113883.2.4.3.11.60.40.2.10.1.1 |
| **Opties** | | |

| «data» | StartDate | |
|---|---|---|
| **Definitie** | The start date of the first use or implant of the medical aid. 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** | | |

| «context» | Indication::Problem | |
|---|---|---|
| **Definitie** | The medical reason for use of the medical aid. | |
| **Datatype** | | |
| **DCM::ConceptId** | NL-CM:10.1.7 | |
| **DCM::ExampleValue** | presbyacusis (ICD10::H91.1) | |
| **DCM::ReferencedConceptId** | NL-CM:5.1.2 | This is a reference to concept Probleem in information model OverdrachtConcern |

| Opties | |
|---|---|

| «data» | Explanation | |
|---|---|---|
| **Definitie** | Comment about use or information on the medical aid used. | |
| **Datatype** | ST | |
| **DCM::ConceptId** | NL-CM:10.1.10 | |
| **Opties** | | |

| «data» | AidAnatomicalLocation | |
|---|---|---|
| **Definitie** | Patient's anatomical location of the medical aid used. | |
| **Datatype** | CD | |
| **DCM::ConceptId** | NL-CM:10.1.6 | |
| **DCM::ExampleValue** | Linker oor 89644007 | |
| **DCM::ValueSet** | AidAnatomicalLocationCodelist | OID: 2.16.840.1.113883.2.4.3.11.60.40.2.10.1.2 |
| **Opties** | | |

| «context» | Location::HealthcareProvider | |
|---|---|---|
| **Definitie** | The healthcare provider at which use of the medical aid 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 concept Zorgaanbieder in information model Zorgaanbieder |
| **Opties** | | |

| «context» | HealthcareProvider | |
|---|---|---|
| **Definitie** | The healthcare provider involved in the indication for use of the medical aid implant. | |
| **Datatype** | | |
| **DCM::ConceptId** | NL-CM:10.1.9 | |
| **DCM::ReferencedConceptId** | NL-CM:17.1.1 | This is a reference to concept Zorgverlener in information model Zorgverlener |
| **Opties** | | |

| «document» | AidAnatomicalLocationCodelist | |
|---|---|---|
| **Definitie** | | |
| **Datatype** | | |
| **DCM::ValueSetId** | 2.16.840.1.113883.2.4.3.11.60.40.2.10.1.2 | |
| **Opties** | | |

| **HulpmiddelAnatomischeLocatieCodelijst** | | **OID: 2.16.840.1.113883.2.4.3.11.60.40.2.10.1.2** |
|---|---|---|
| Codes | Coding Syst. Name | Coding System OID |
| SNOMED CT: <<91723000 \| anatomical structure \| | SNOMED CT | 2.16.840.1.113883.6.96 |

| «document» | ProductIDCodelist |
|---|---|

| | | |
|---|---|---|
| **Definitie** | | |
| **Datatype** | | |
| **DCM::ValueSetId** | 2.16.840.1.113883.2.4.3.11.60.40.2.10.1.3 | |
| **Opties** | | |

| **ProductIDCodelijst** | | **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::ValueSetId** | 2.16.840.1.113883.2.4.3.11.60.40.2.10.1.1 | |
| **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 |
| Alle waarden | UNSPSC | 2.16.840.1.113883.6.302 |

## 1.7 Example Instances

| Begin Datum | Product | | Hulpmiddel Anatomische Locatie | Indicatie | Locatie | | Toelichting |
|---|---|---|---|---|---|---|---|
| | ProductID | ProductType | | ProbleemNaam | Organisatie Naam | Afdeling Specialisme | |
| 08-03-2012 | 42192210 | Rolstoel | | Multiple sclerose | | | Kan korte afstanden lopen |

| Begin Datum | Product | | Hulpmiddel Anatomische Locatie | Indicatie | Locatie | | Toelichting |
|---|---|---|---|---|---|---|---|
| | ProductID | ProductType | | ProbleemNaam | Organisatie Naam | Afdeling Specialisme | |
| 2007 | 42144000 | Gehoorapparaat | Roor | Presbyacusis | St. Franciscus Gasthuis | Audiologie | Apparaat niet zichtbaar (diep in de gehooringang) |

## 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 UNPSPSC for documenting the type of medical aid 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

This Health and Care Information Model (a.k.a Clinical Building Block) has been made in collaboration with several different parties in healthcare. These parties asked Nictiz to manage good maintenance and development of the information models. Hereafter, these parties and Nictiz are referred to as the collaborating parties. The collaborating parties paid utmost attention to the reliability and topicality of the data in these Health and Care Information Models. Omissions and inaccuracies may however occur. The collaborating parties are not liable for any damages resulting from omissions or inaccuracies in the information provided, nor are they liable for damages resulting from problems caused by or inherent to distributing information on the internet, such as malfunctions, interruptions, errors or delays in information or services provide by the parties to you or by you to the parties via a website or via e-mail, or any other digital means. The collaborating parties will also not accept liability for any damages resulting from the use of data, advice or ideas provided by or on behalf of the parties by means of this Health and Care Information Model. The parties will not accept any liability for the content of information in this Health and Care Information Model to which or from which a hyperlink is referred. In the event of contradictions in mentioned Health and Care Information Model documents and files, the most recent and highest version of the listed order in the revisions will indicate the priority of the documents in question. If information included in the digital version of this Health and Care Information Model is also distributed in writing, the written version will be leading in case of textual differences. This will apply if both have the same version number and date. A definitive version has priority over a draft version. A revised version has priority over previous versions.

## 1.18 Terms of Use

## 1.19 Copyrights