

Declaration of Intent Uniform Dataset

This agreement document focuses on a more efficient and practical guide in the implementation of the European regulations MDR and IVDR, the Dutch LIR registration obligation and the Covenant on Safe Medical Technology (2016) for all parties involved in the Netherlands, namely manufacturers, importers, distributors, and healthcare institutions.

The purpose of this document is to establish the use and framework of a uniform dataset for all medical products used in Dutch healthcare institutions, integrated in GDSN, for the healthcare institutions affiliated with the NVZ, NFU, ZKN and the manufacturers, importers and distributors affiliated with FHI, FME and Nefemed. We conform to the uniform dataset until it is fully incorporated into GDSN. These fields will also be integrated into the GS1 ECHO data model.

For the time being, the dataset is not yet fully integrated into GDSN, it is therefore recommended to apply the agreed dataset when requesting information.

Other relevant regulations:

- Healthcare Quality, Complaints and Disputes Act (WKKGZ).
- Regarding medical devices, this *document* is based on the legal definition from the Medical Devices Act. *It implements Regulation (EU) [2017/745](#) (MDR) and Regulation (EU) [2017/746](#) (IVDR).*

The dataset does not yet answer specific questions about medical equipment and software.

Each organization takes care of the accuracy and reliability of the fields entered in this dataset.

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The industry associations NVZ, NFU, ZKN, Nefemed, FHI, FME, VDSMH, specialists from the healthcare sector (e.g., LNAG), GS1 and various individual medical suppliers *speak out to promote the use of the uniform dataset* (version 1 see appendix).

Together they also express the hope that this dataset will be integrated into the GDSN data network at short notice (mid-2022). A proposal for a sounding board group to work together to consider the further expansion of the set is being investigated with GS1.

The current working group takes care of the communication to all members to stimulate and support the use and filling of the uniform dataset fields, so that all parties involved in the Netherlands have the same uniform and correct information.

Attachments:

- Final version Uniform Dataset
- History of the origin of and future plans for the dataset
- Roadmap Reference set GDSN ECHO data model, which dataset fields are already in GDSN and which are not
- Current ECHO data model – field list in Excel

Frames of reference and sources:

- Tools in the context of MDR and IVDR of NFU and NVZ on Kennisnet ([link](#))
- LIR Dutch Implant Registry and MDR (*EU Regulation 2017/745*) and IVDR (*EU Regulation 2017/746*)
- Agreement on the Safe Application of Medical Technology in the medical specialist care of August 2016 ([link](#))
- Agreements on unique coding medical devices ([ADC](#))

Endorsed by:

