

Why did we develop a Uniform Dataset in the Netherlands for all medical products used in Dutch healthcare institutions?

In the run-up to the establishment of the Uniform Dataset for all medical products used in Dutch healthcare institutions, concerns have been expressed since 2019 (independently from various suppliers and healthcare institutions) about the inefficiency and even unworkability in requesting the desired data (to register and pass on to the patient) in the context of Dutch Implant Registry (LIR) and European Medical Device Regulation (MDR).

All organizations involved struggle with poor or non-digitally available and/or fragmented availability of the requested information, which often has to be retrieved and brought together from various (different!) ICT systems. At the moment, healthcare institutions do not have all the information they have to register themselves and which they also need to be able to provide to the patient. For optimal patient safety, healthcare institutions want to be able to trace all medical items. In addition, the lack of this information, both for the healthcare institutions as suppliers/distributors, makes it impossible to respond adequately and provide information if production problems and shortages arise. Especially during Corona and Brexit, this has now been sufficiently demonstrated.

In the attached declaration of intent, the result is brought together of consultations between the representatives of the relevant umbrella organizations such as NVZ, NFU, ZKN, Nefemed, FHI, FME, VDSMH, expert networks from the healthcare sector (such as LNAG), GS1 and from various individual medical suppliers, namely Mediq, Medtronic, B. Braun, OneMed and Johnson & Johnson. All endorse the need for a unified dataset and are committed to promoting the use of the dataset as a format for the exchange of information until it is fully incorporated into GDSN. These fields will also be integrated into the GS1 ECHO data model. The letter of intent will also be shared with VWS and IGJ so that they are familiar with it and able to contribute.

Where are we going?

With the legal obligation, the need is growing for more and higher quality data. There is currently no standard method of exchanging data; requests are done in various ways and vary per requester.

In the Netherlands, it has been agreed upon in the context of the ADC (agreements on unique coding of medical devices) that GDSN is the standard for the exchange of product master data. Based on the Declaration of Intent Uniform Dataset, it was agreed to further expand the existing ECHO dataset. By means of a roadmap, it will be mapped out which fields are already present, which fields are still missing and when they will be added. The further expansion of this uniform dataset will be shaped by the sounding board group to be established with representatives of the various parties involved. The starting point is that the manufacturer is the source for the product dataset to be exchanged, which guarantees the 'single source of truth'. The sounding board group will also issue advice on the desired data quality and the resulting measures.

GDSN: GDSN is short for Global Data Synchronization Network and is a GS1 standard for data sharing. GDSN makes it possible for every company, in every market and in every country, to share product information.

GS1's international network consists of several data pools that speak the same language. Suppliers can load product information into a data pool within the GDSN network, while clients (receivers) may

retrieve the same product information via another data pool. GDSN works with standardized data. All information is entered, stored and shared with recipients in the same way. Suppliers decide with whom they share their data and recipients decide from whom they want to receive data. In the Netherlands, the GS1 Data Source data pool is used to share product information via GDSN.

ECHO: ECHO is short for Extending the Collaboration of Healthcare Organizations and is a collaboration between GS1 member organizations and healthcare stakeholders to align efforts and create a clear strategy for the exchange of product data via GDSN (Global Data Synchronization Network).

Healthcare providers are under constant pressure to provide good care at lower costs, and it is also important to reduce errors and optimize processes. Manufacturers, on the other hand, face a deluge of requirements from different countries with different regulations, languages and business needs. The ECHO initiative focuses on harmonizing market strategies and data requirements of different countries in order to maximize the benefits of using GDSN.