Joint Declaration

Standardised Exchange of Medical Device Data

This Joint Declaration aims to support more efficient logistics and commercial collaboration between the Danish Regions and suppliers of medical devices.

The Joint Declaration has been prepared jointly by Medicoindustrien, Danish Regions, and GS1 Denmark and is effective from May 2026.

The declaration covers collaboration between manufacturers, importers, distributors, and the regions in Denmark and establishes a shared commitment to the use of a standardised dataset for medical devices based on the European ECHO data model.

The initiative is driven by a common ambition to realise the efficiency gains associated with establishing a harmonised dataset for medical devices and enabling the exchange of information through a global data synchronisation platform. As data becomes increasingly critical to collaboration across the healthcare supply chain, the parties recognise the importance of a common and scalable approach to data exchange.

Medicoindustrien and the regions have discussed data requirements through a series of network meetings concluding in January 2026. The parties agree that medical device data should be exchanged based on the agreed data model and have aligned on which data fields are essential to collaboration, including the status of each field (mandatory, conditionally mandatory, or optional).

Each organisation acting as a data provider is responsible for ensuring the quality, accuracy, and completeness of the data entered into the standardised dataset. Furthermore, the parties agree that the implementation framework must take into account the varying capabilities and readiness levels of all stakeholders involved.

The parties agree that:

- The common dataset for medical devices shall constitute the foundation for the exchange of medical device data. In the initial phase, however, the dataset will not include data related to the subcategory Software as a Medical Device (SaMD).
- The Global Data Synchronisation Network (GDSN) shall serve as the primary channel for the exchange of product data from suppliers to the regions in Denmark. Should the parties identify gaps in the information currently supported by GDSN, they will collaborate to ensure that such requirements are incorporated into the relevant global standards.
- Requirements for exchanging product data through a global data synchronisation platform should form part of contractual agreements relating to medical devices in order to support the most efficient and streamlined method of data exchange.
- The regions in Denmark are at different stages of readiness with regard to receiving structured product data. Consequently, a phased implementation period will be required for manufacturers, suppliers, and the regions alike. The first regions are expected to be ready to receive data by the end of 2025, while others will need to adapt their IT systems to support data integration.
- A user group will be established under the auspices of GS1 Denmark to monitor developments related to data exchange and data quality, facilitate knowledge sharing, and support the continued development and adaptation of the data model.

Prepared jointly by:

Region Sjælland – vi er til for dig
GS1 Denmark
Region Nordjylland
Region Hovedstaden
Medico Industrien – Medtech Denmark
Region Midtjylland
Region Syddanmark