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Dutch market agreement on standardised, automated and global sharing of CSSD information

Jolanda Buijs – Erasmus MC Rotterdam (Netherlands)

Jolyn van der Beek – GS 1 Netherlands

World Federation for Hospital Sterilisation Sciences

Agenda

1. History of medical device documentation
2. Implications for hospitals and medical device suppliers
3. National working group in the Netherlands
4. The role of the Dutch Association of Experts on Sterilisation of Medical Devices (VDSM
5. The solution in Global Data Synchronisation Network (GDSN)
6. Relation GDSN and barcode
7. What's in it for you!

Legislation in the Netherlands

Legislation on sterilised medical devices in hospitals (1983 and 2004)

Mandatory documentation about:

- Equipment for cleaning, disinfection and sterilisation
- To be sterilised medical devices in relation to the applied reprocessing methods

2011: Covenant on Safe Application of Medical Technology in hospitals

Impact on hospitals and suppliers

- Wide variety in how hospitals request product data
- Non-automated process:
  - Risk of incorrect product data
  - Labor-intensive for both hospitals and suppliers
- Product data not up-to-date

Meeting “RAPS Netherlands Chapter” - May 2019

(Regulatory Affairs Professionals Society)

Impactful collaboration

NVZ Nederlandse Vereniging van Ziekenhuizen

NFU NEDERLANDSE FEDERATIE VAN UNIVERSITAIR MEDISCHE CENTRA

zkn ZELFSTANDIGE KLINIEKEN NEDERLAND

VDSMH VERENIGING VAN DESKUNDIGEN STERIELE MEDISCHE HULPMIDDELEN

FME POWERED BY DUTCH TECHNOLOGY

FHI MEDISCHE TECHNOLOGIE

Inag

MEDIQ

GS1 Nederland

B|BRAUN SHARING EXPERTISE

Johnson & Johnson MEDICAL DEVICES COMPANIES

NEFEMED

Medtronic Further, Together

ONEMED

Focus VDSMH

Quick and easy access to product data:

- Essential information for medical device assessment
- Preparation of purchase file

VDSMH
VERENIGING VAN DESKUNDIGEN STERIELE MEDISCHE HULPMIDDELEN

Important product data for the Sterilisation Expert?

- Identification of the medical device
- Compliance to MDD / MDR (CE-certificate, Declaration of Conformity)
- Instructions for cleaning, desinfection and sterilisation
- Product image of (set of) instruments
- Education of the CSSD-staff

VDSMH
VERENIGING VAN DESKUNDIGEN STERIELE MEDISCHE HULPMIDDELEN

Solution

Product data standardised, digitally and real-time available!

Product data available through a digital connection to the instrument track & trace system in the Central Sterile Supply Department (CSSD)

How are we going to do that?

- → Not all essential product data available
- → Limited access
- → No possibility for integration with internal hospital systems (EHR/ERP)

EUDAMED

Why did the workgroup choose for GS1?

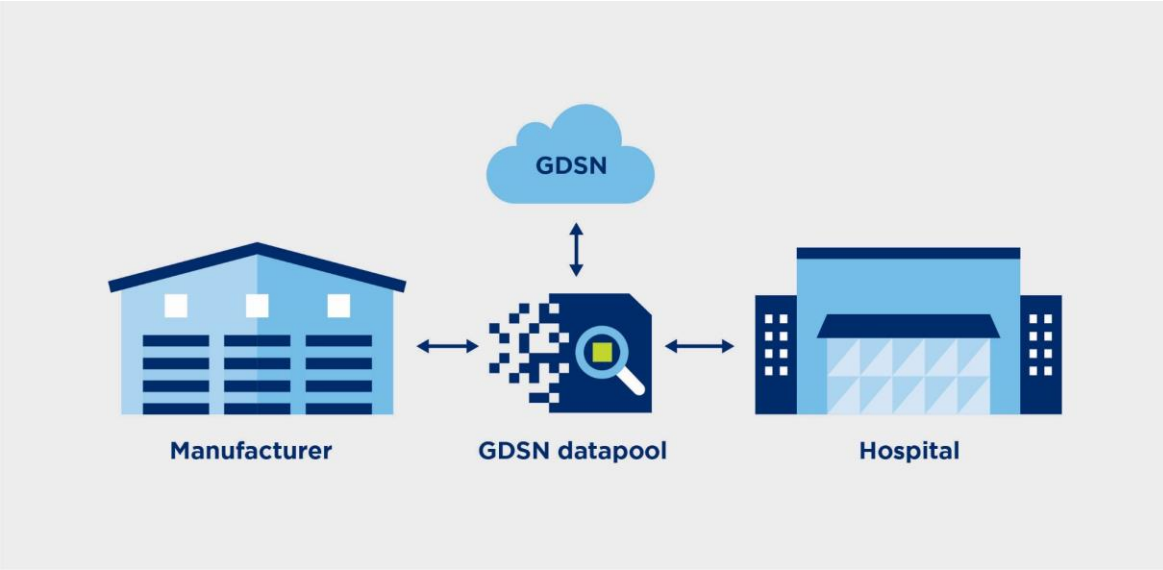



- Global sharing of product data through GDSN
- International not-for-profit partner, active in 116 countries
- 50 years of standardised product identification
- Accredited issuing agency for Unique Device Identification (UDI)

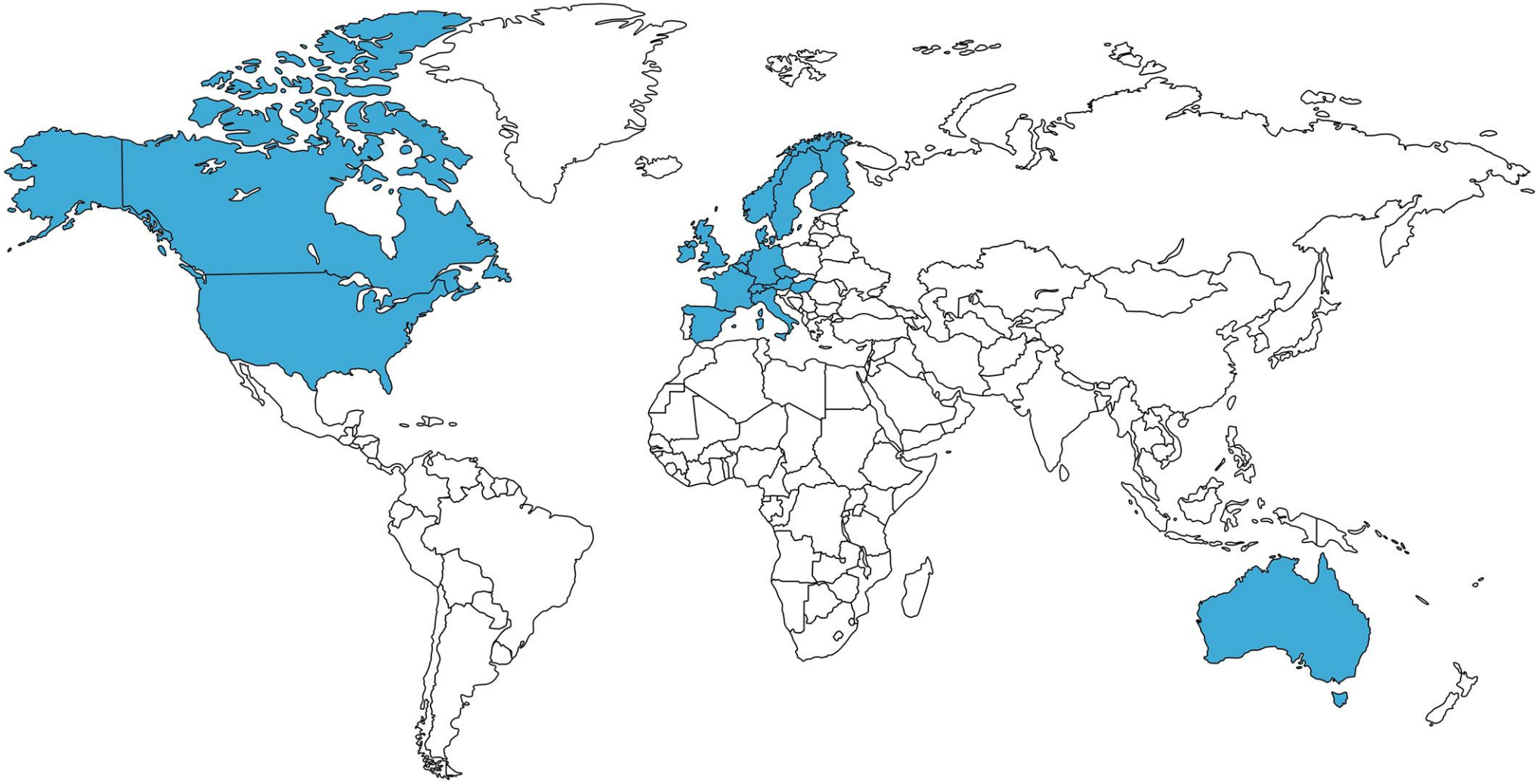
Uniform sharing of product data: GDSN

Through the Global Data Synchronisation Network (GDSN): suppliers and hospitals easily share product data worldwide

95% of all Dutch hospitals are connected, mainly due to the national regulation: Dutch Implant Registry (LIR)



Use of GDSN in Healthcare



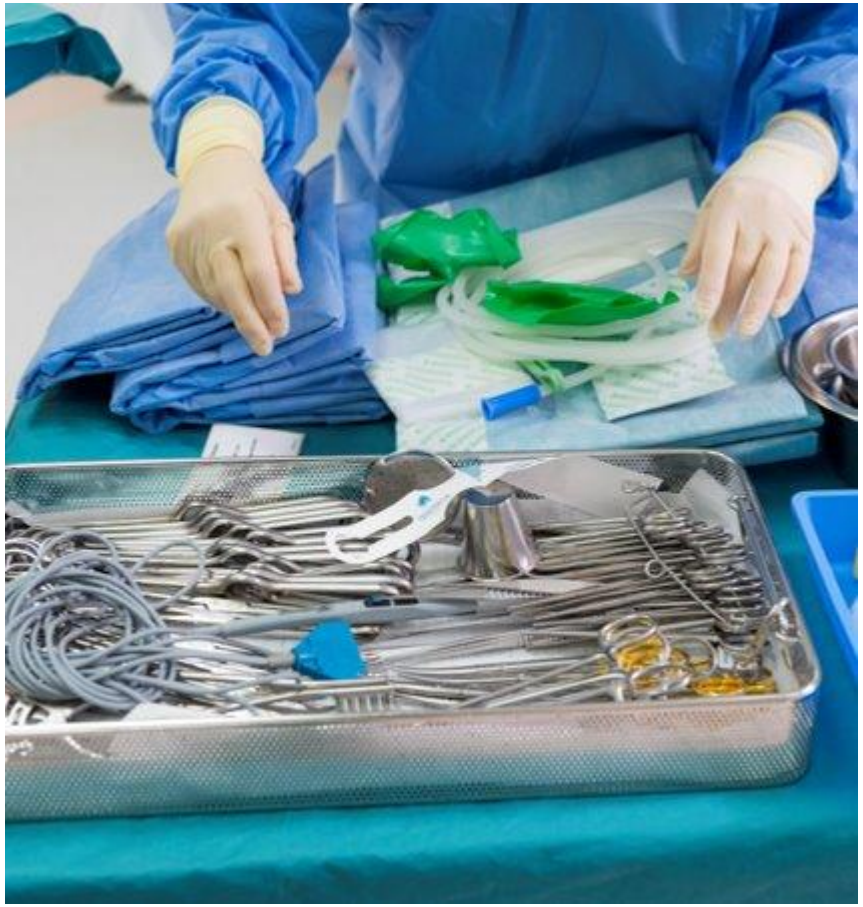
Use of product data medical devices

For product files of all medical devices:

- Sterile / to sterilise or not sterile products
- Purchasing files, loaner sets, consigment
- Both reusable and single use devices

Data on reprocessing

- Purchasing information
- Logistical data



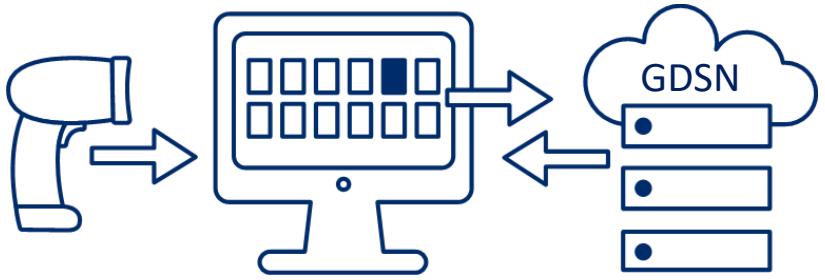
Product data behind the barcode

Scanning barcodes and using product data from GDSN is not new

Existing processes:

- Procurement/purchasing
- Logistics
- Operating room
- Registries

GDSN product data can be connected with:



Electronic Health Record (EHR)
Enterprise Resource Planning (ERP)
Track & Trace System CSSD

Unique Device Identification (UDI) on reusable devices

Classes medical devices	Assign UDI	UDI on label
Class III	26 May 2021	26 May 2021
Classes IIa en IIb	26 May 2021	26 May 2023
Class I	26 May 2021	26 May 2025
UDI on reusable devices	26 May 2021	+ 2 years

Transition period from MDD to MDR for certain devices:
Class III and IIb: 31 December 2027
Class IIa and I: 31 December 2028

What have we achieved together?

The Uniform Dataset

- Complete and standardised dataset for all medical devices
- Fully integrated in GDSN → One single source of truth
- Up-to-date
- Less error-prone
- More efficient
- Real-time available

The role of GS1

Support for suppliers and hospitals
with product identification, data-exchange via GDSN and standardisation for regulatory compliance

- Global collaboration
- Connections with local GS1 organisations (including government, industry associations, suppliers and hospitals)