Medicines & Healthcare products Regulatory Agency

Traceability – regulatory aspects

GS1 Healthcare Conference – 10 April 2019

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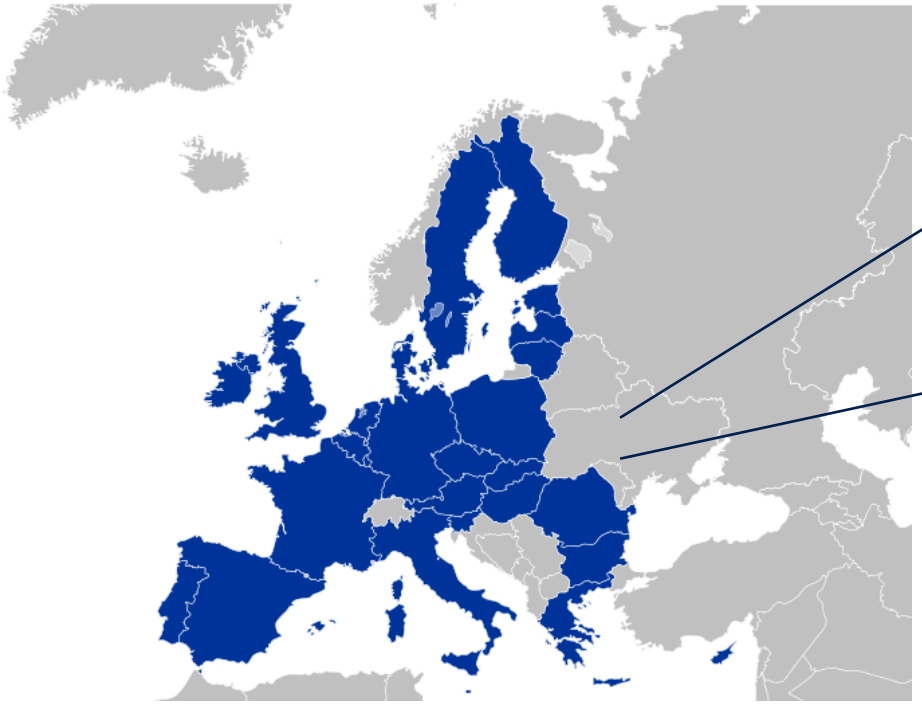
CPRD NIBSC MHRA

Key topics

- Overview of new Medical Device Regulations
- Traceability requirements
- Supply chain – recalls – implant cards

New medical device regulations
Two EU Regulations



MDR - Regulation (EU) 2017/745 – published 5 May 2017

Medical Devices Regulations

in-Vitro Diagnostic Devices Regulations

IVDR - Regulation (EU) 2017/746 – published 5 May 2017

UDI assignment and submission of UDI core data elements to the European database by 26 May 2020 (medical devices) or 26 May 2022 (IVDs)

New European Regulations: major upgrade

UDI is one small(!) part of a complete revamp of the European Medical Device (MDR) and IVD (IVDR) regulations

Council Directive 93/42/EEC - 14 June 1993	Regulation (EU) 2017/745 – 5 May 2017
60 pages	175 pages
23 Articles	123 Articles
12 Annexes	17 Annexes

UDIs enhance traceability and improve post-market safety

Using a Unique Device Identification (UDI) system **based on international guidance** should significantly enhance the post-market safety of medical devices by:

- improving incident reporting
- better targeting of recalls
- better monitoring by competent authorities
- reducing medical errors
- fighting against counterfeit devices
- improving purchase-policy and stock-management by hospitals

Regulation (EU) 2017/745: Recital 41

UDI with a GTIN, Expiry and Serial Number

GS1 = UDI

(though other UDI systems may also be acceptable!)

Translation UDI to GS1

UDI Unique Device Identification	**GS1 Standards** Product Identification
UDID Data Elements linked to the Device Identifier	**GDSN** Attributes mapped to each UDID data element
DI = Device Identifier (DI)	**GTIN** Global Trade Item Number
Production data is not stored in UDI or GDSN databases	
PI = Production Identifier (PI) (if applicable) Production Identifier data will vary by medical device type and manufacturer current practice.	**AI** Application Identifiers (AI) • Expiration Date AI(17) e.g. 141120 • Lot/Batch AI(10) e.g. 1234AB • Serial Number AI(21) e.g. 12345XYZ
DI + PI = UDI	**GTIN -or- GTIN + AI(s) = UDI**

Requirements of the European UDI system

UDI system should allow the identification and traceability of medical devices (excludes custom-made and clinical trial devices) and IVDs

UDIs should be in two parts:

- device identifier (UDI-DI) – *static*
- production identifier (UDI-PI) – *dynamic*

UDIs should be placed on device labels (machine readable + plain text)

UDIs should be stored by manufacturers, importers, distributors and hospitals (using electronic means)

Centralised European UDI database (part of Eudamed)

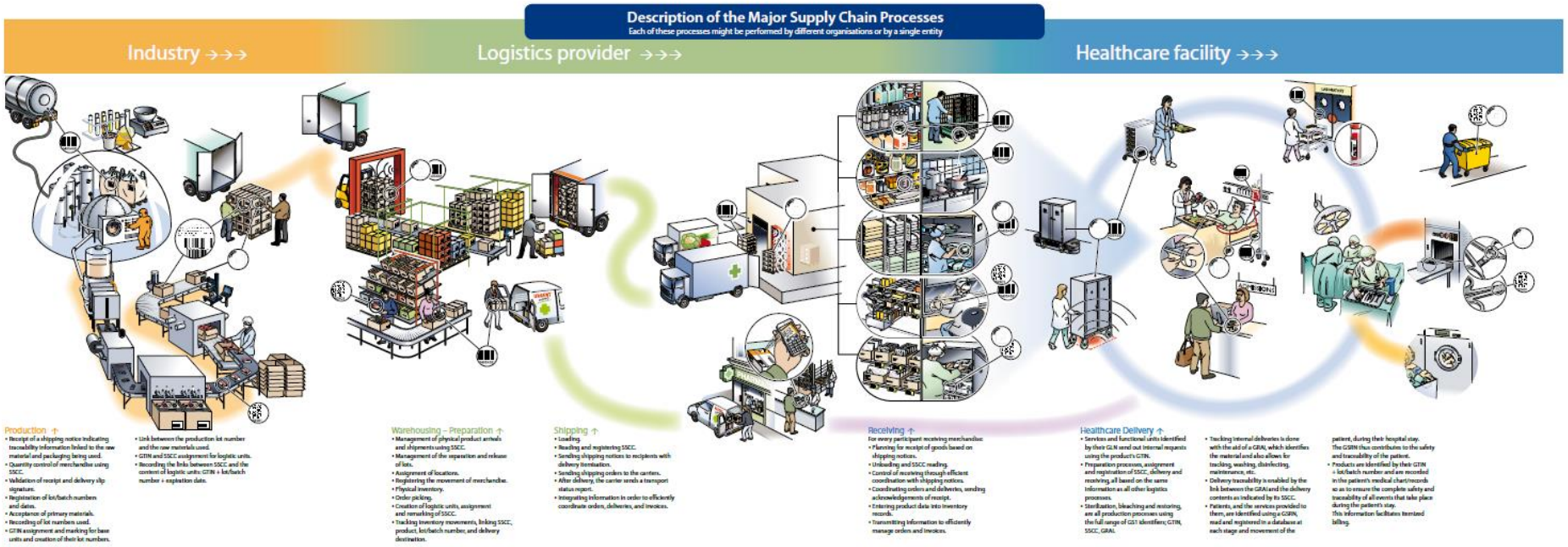
How UDIs should be used

UDI should be placed on the labels of devices and must:

- be used for reporting serious incidents and field safety corrective actions (recalls)
- be referenced in information provided to patients who have received implants (implant cards or electronic)
- be included in technical / regulatory documentation

Traceability throughout the supply chain

Manufacturer → importer/distributor → hospital → patient

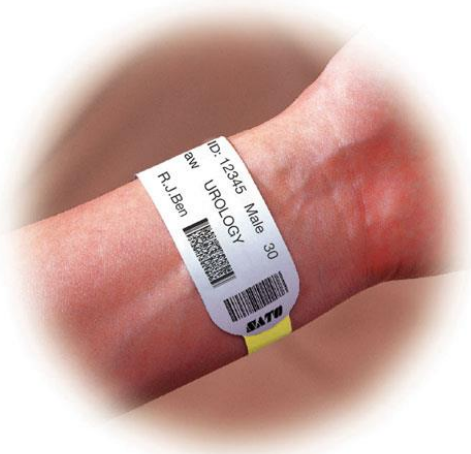


Recording of UDIs

Manufacturers, importers, distributors and hospitals must store and keep UDIs (both device identifier and production identifiers) by electronic means

SCAN4SAFETY
Patient, Product, Place, Process.

Using UDI / GS1 standards improves patient safety – implant tracking and surveillance



- Implant / patient track-&-trace
- Post-market safety monitoring

MHRA Medical Device Alerts

Medical Device Alert

MDA/2015/024 Issued: 25 June 2015 at 14:00

Metal-on-metal (MoM) hip replacements:
Birmingham Hip™ Resurfacing (BHR) system (Smith & Nephew Orthopaedics)

Summary

Higher than expected revision rate for certain patient groups implanted with the Birmingham Hip Resurfacing (BHR) system. Guidance provided on implantation and patient management.

Action

- Do not implant BHR devices in:
  - > female patients
  - > patients requiring femoral heads sized 46mm or smaller.
- Only use 48mm BHR heads in the specific circumstance of intra-operative downsizing from a pre-operatively templated 50mm to a measured 48mm at the time of surgery.
- Return all unused BHR femoral heads sized 46mm and smaller and their corresponding acetabular and dysplasia cups to the manufacturer.
- Follow up patients implanted with BHR hips that fall within the scope of this Medical Device Alert i.e.:
  - > all symptomatic patients
  - > all female patients
  - > all patients implanted with head sizes 46mm or smaller

in line with recommendations in the table below **(based on the advice given in MDA/2012/036)**

	Management recommendations for patients implanted with BHR hips that fall within the scope of this Medical Device Alert
Patient follow-up	Annually for the life of the implant
Imaging: MARS MRI or ultrasound	Recommended in all cases
1st blood metal ion level test	**Yes**
Results of 1st blood metal ion level test	Blood metal ion level >7ppb indicates potential for soft tissue reaction
2nd blood metal ion level test	**Yes** - 3 months after 1st blood test if result was >7ppb
Results of 2nd blood metal ion level test	Blood metal ion level >7ppb indicates potential for soft tissue reaction especially if greater than previously
Consider need for revision	If imaging is abnormal and/or blood metal ion levels rising

Table footnotes:
- Blood metal ion testing to be in whole blood
- 7 parts per billion (ppb) equals 119 nmol/L cobalt or 134.5 nmol/L chromium

Device details

Catalogue number	**Unique Device Identifier (GS1)**
BHR head	
74121138	03596010502766
74123140	03596010552402
74121142	03596010502773
74123144	03596010552419
74121146	03596010502780
BHR acetabular cup	
74120144	03596010502537
74120146	03596010502544
74122146	03596010565792
74122148	03596010552266
74120148	03596010502551
74120150	03596010502568
74122150	03596010552273
74122152	03596010552280
74120152	03596010502575
74120154	03596010502582
BHR dysplasia cup	
74120246	03596010502650
74122248	03596010552358
74120250	03596010502667
74122252	03596010552365
74120254	03596010502674

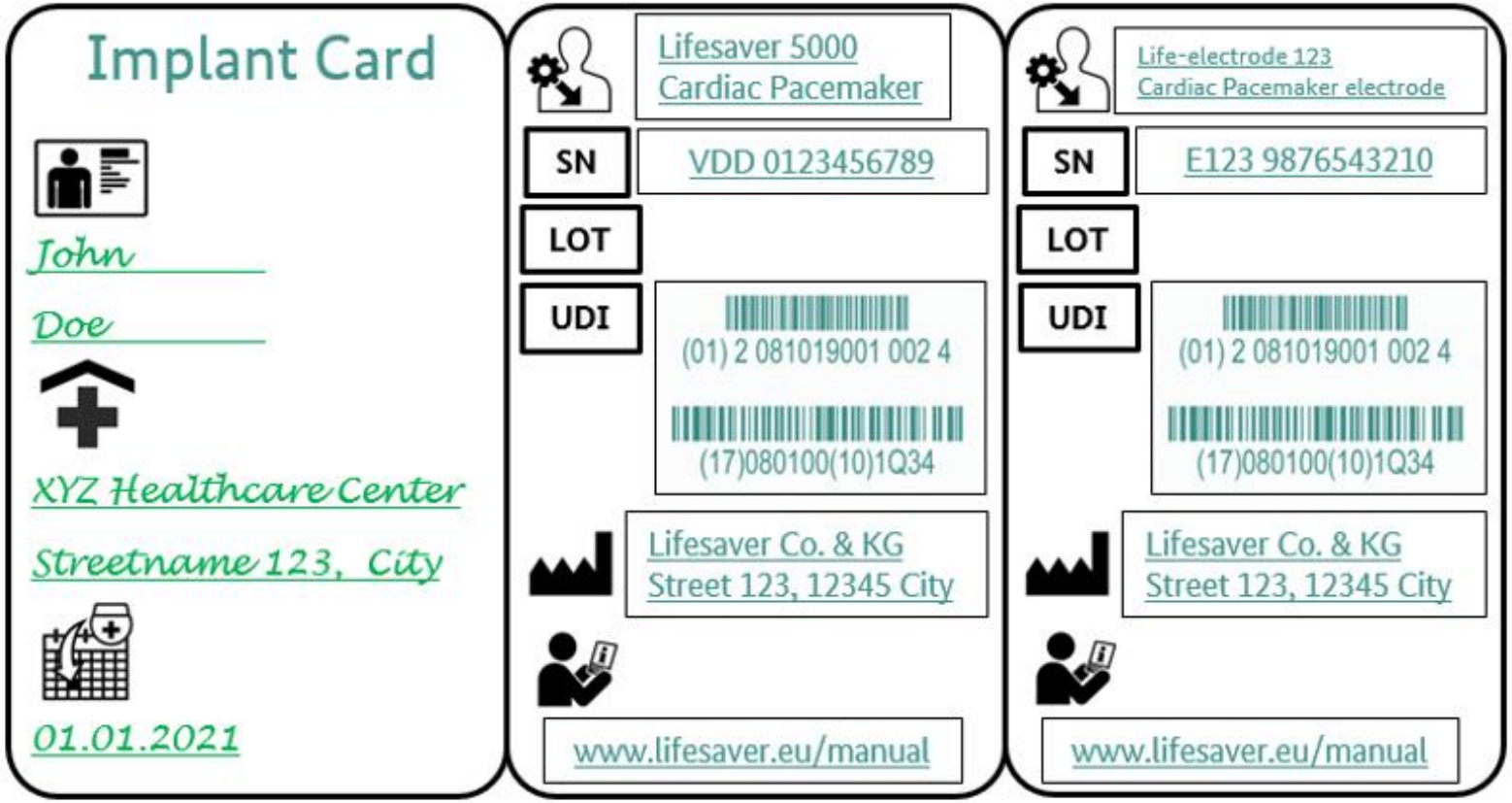
Field Safety Corrective Actions and Recalls

Manufacturers should:

- Reference UDIs in their Field Safety Notices (FSNs)
- Send customers and distributors electronic lists of all products affected by a FSCA in an Excel spreadsheet

> “These recommendations give healthcare providers everything they need to implement more automated and secure GS1-based FSCA processes, in line with the Department of Health eProcurement strategy.”
>
> - Jackie Pomroy, Head of Supply Chain at NHS South of England Procurement Services

European implant cards



UDI with a GTIN, Expiry and Serial Number

Thank you

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