Medical device regulation and the MHRA devices registration system

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#GS1UDIForum

Medical device regulation and the MHRA devices registration system

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Agenda

- Overview of UK Medical Device Regulation
- UDI requirements in Great Britain and Northern Ireland and the Medicines and Medical Devices Act
- MHRA Devices Registration System
- UDI inclusion in both MHRA and manufacturer safety communications

Standstill Position

- The transition period between the UK and the EU ended on 31 December 2020
- 2.5 year ‘standstill period’
- Different regulation in Great Britain (England, Wales, Scotland) and Northern Ireland due to the Northern Ireland Protocol
- Northern Ireland will have access to the EU Single Market and it will continue to align with EU rules for medical devices

Standstill Position

Great Britain

- EU MDR/IVDR not implemented
- Recognition of the CE marking until 30 June 2023
- UKCA marking required after 30 June 2023
- Approved Bodies can now conduct assessments for the UKCA mark

Northern Ireland

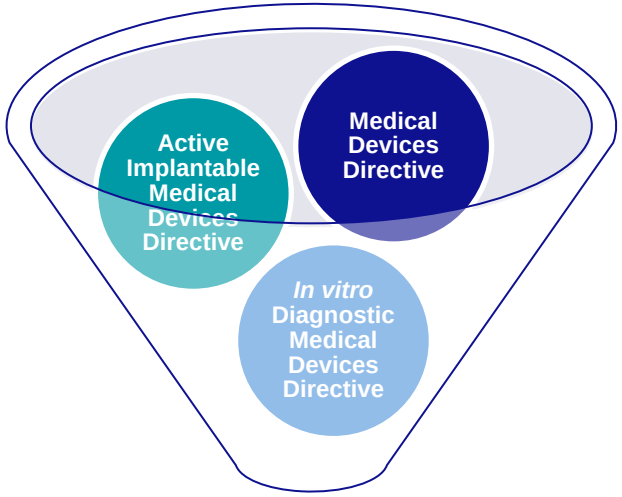
- EU MDR/IVDR implemented with EU timeline
- Devices must be CE or CE UKNI marked
- CE UKNI applied where UK Notified Body used for conformity assessment

UK Legislation

- Medical devices are regulated in the UK under the **UK Medical Devices Regulations 2002** (UK MDR 2002)

- The UK MDR 2002 is based on existing EU legislation which has been transposed into UK law

- **The Medicines and Medical Devices Act (2021)**:
  - allows us to amend the UK MDR 2002
  - consolidates enforcement provisions
  - introduces civil sanctions
  - allows for enhanced data sharing
  - enables the creation of a devices register (MHRA) and a medical device information system (NHS Digital)



UK Medical Devices Regulations 2002

(as amended)

Medicines and Medical Devices Act 2021

Future Regulation of Medical Devices in Great Britain

Attractive world-class regulatory system which prioritises patient safety

Early 2021	Late 2021-Early 2023	July 2023
• MMD Act in force • Informal consultation with stakeholders	• Formal public consultation • Agree position and finalise secondary legislation	• Stop recognition of CE marking in GB • New medical device regulatory framework in force

We will take into consideration international standards and global harmonisation in the development of our future system

MHRA

UDI requirements in GB and NI

Medicines & Healthcare products Regulatory Agency

Unique Device Identification

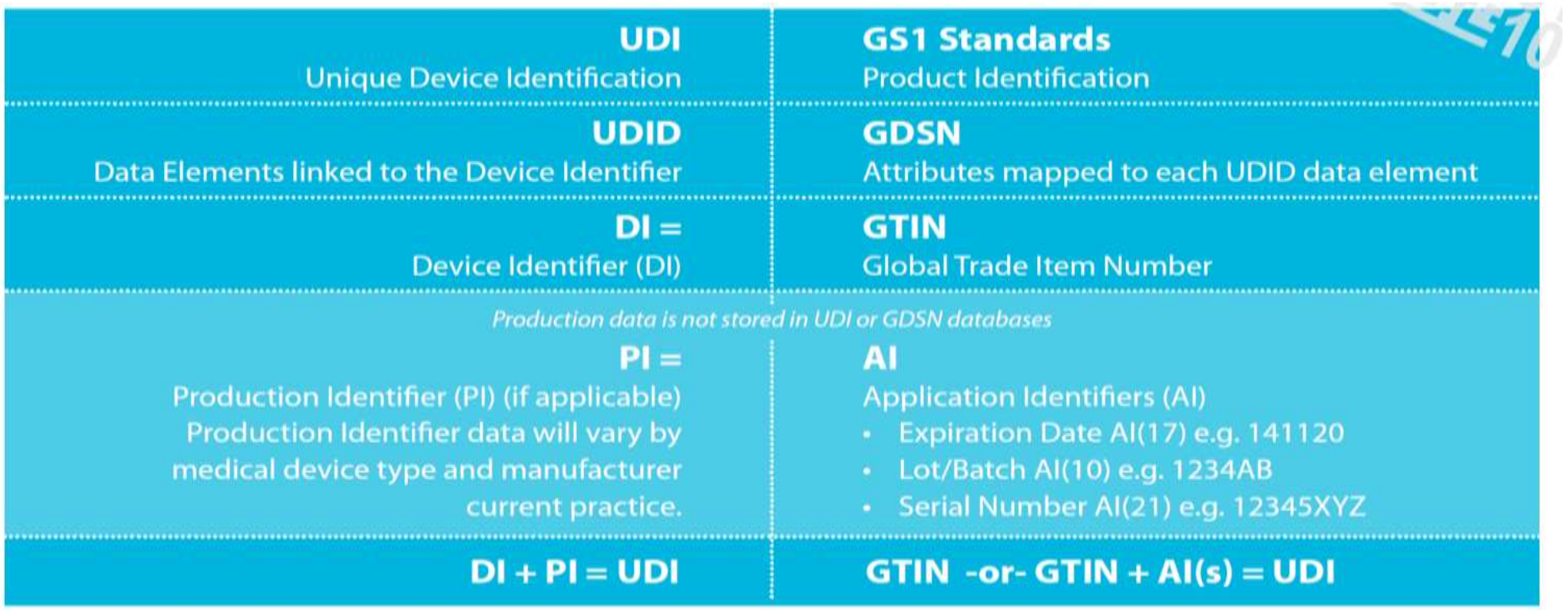
UDI Definition

- *a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard. It allows the unambiguous identification of a specific device on the market.*

UDI is made up of two components

- *UDI-Device Identifier (UDI-DI) – specific to a manufacturer and a device*
- *UDI-Production Identifier (UDI-PI) – identifies the unit of device production*

Translation UDI to GS1



Basic UDI-DI	GMN Global Model Number

UDI requirements in Northern Ireland

Manufacturers must assign UDIs to all of the medical devices / IVDs before they place them on the market

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

UDIs should be:

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

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

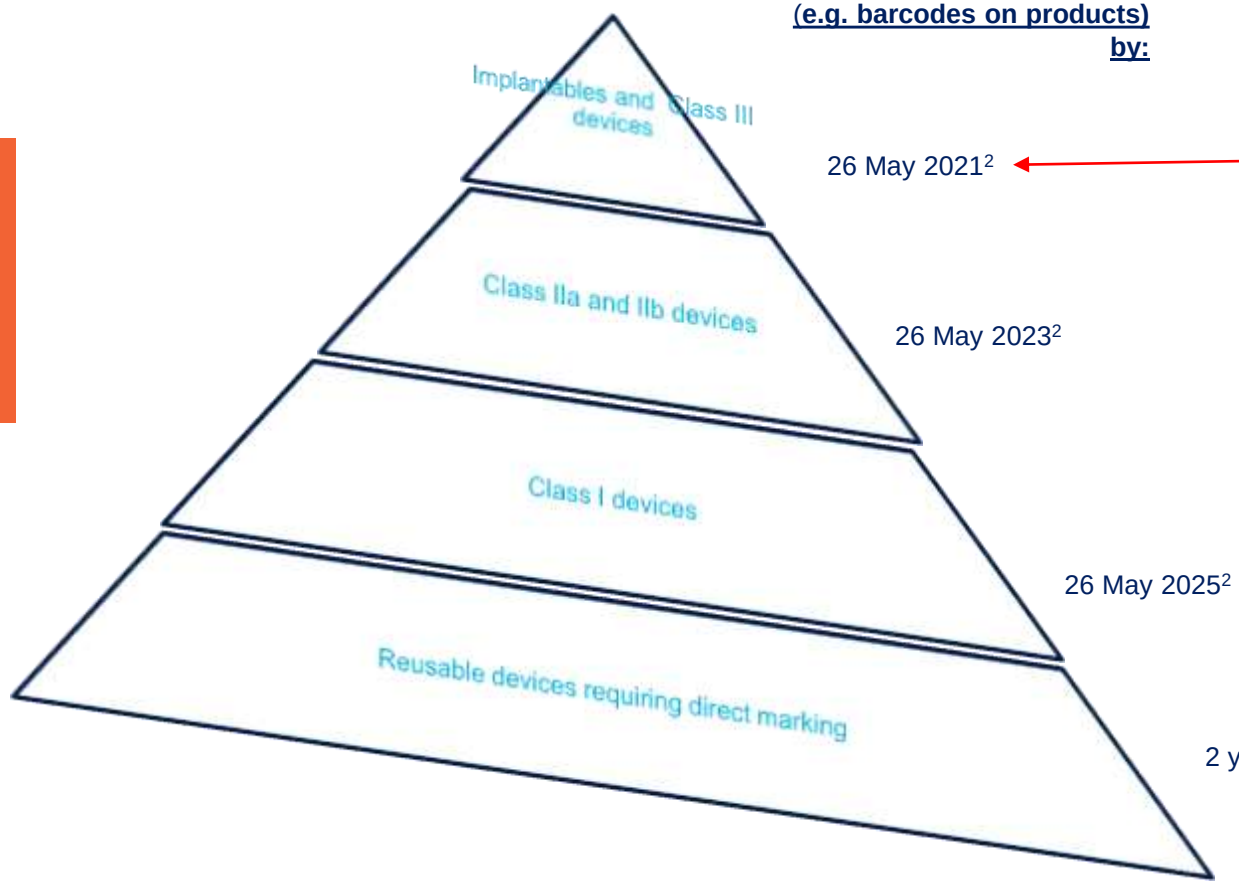
Manufacturers should submit UDI data to the EUDAMED database

NI UDI timelines – medical devices

All classes of devices

- **UDI assignment by 26 May 2021**
- **Submission of UDI core data elements to Eudamed is required 24 months after the EU notice that Eudamed is fully functional is published[1]**

Placement of the UDI carrier (e.g. barcodes on products) by:



26 May 2021[2]

Many (most?) implantable devices ***already include*** UDIs on their labels

26 May 2023[2]

26 May 2025[2]

2 years after the date applicable for its respective class of devices[3]

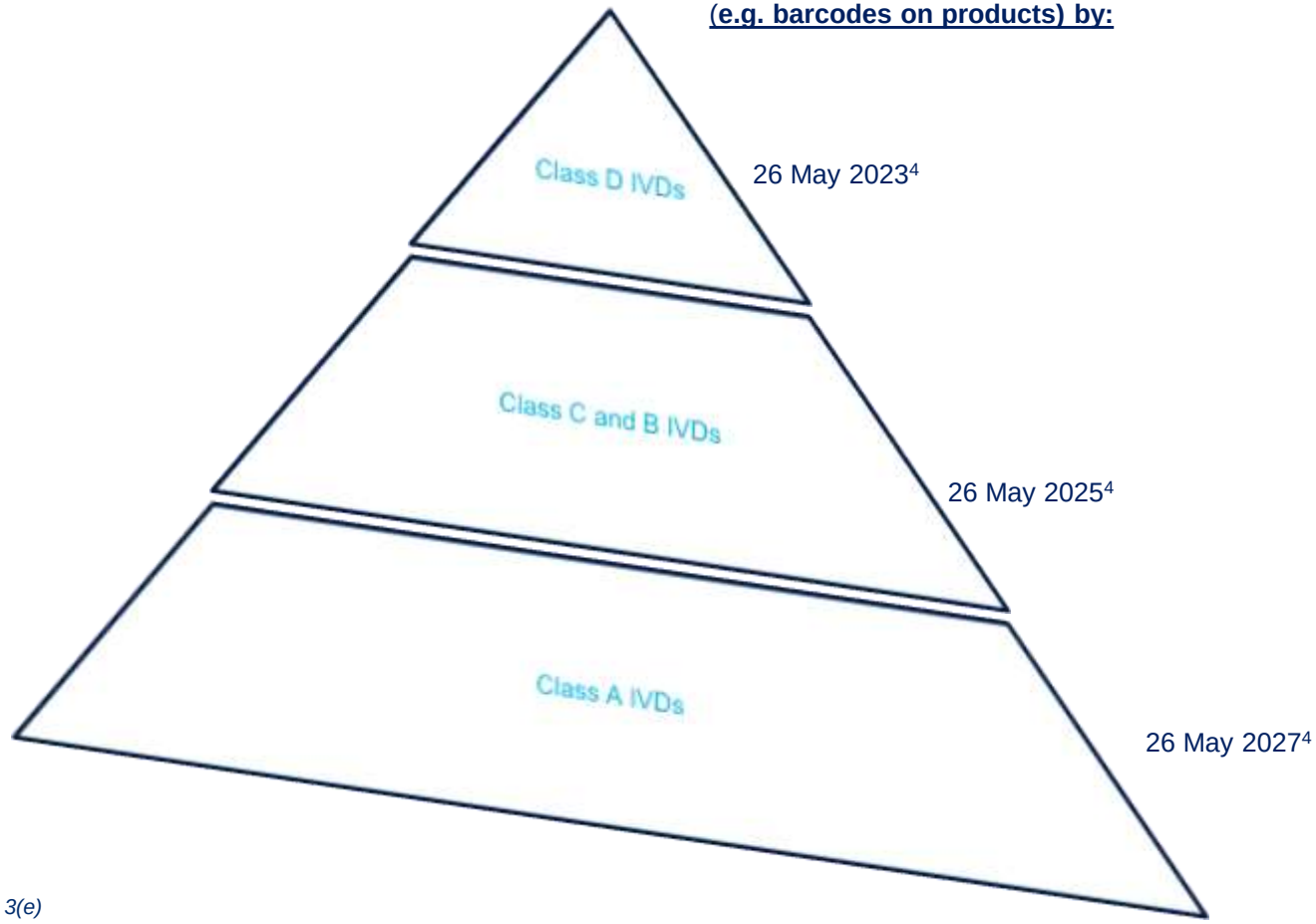
1. *MDCG 2019-4 Timelines for registration of device data elements in Eudamed*
2. *Regulation (EU) 2017/745 Regulation (EU) 2017/745 - 5 May 2017 - Article 123, paragraph 3(f)*
3. *Regulation (EU) 2017/745 - 5 May 2017 - Article 123, paragraph 3(g)*

NI UDI timelines – IVDs

All classes of IVDs

- **UDI assignment by 26 May 2022**
- **Submission of UDI core data elements to Eudamed is required 24 months after the EU notice that Eudamed is fully functional is published[1]**

Placement of the UDI carrier (e.g. barcodes on products) by:



4. Regulation (EU) 2017/746 - 5 May 2017 - Article 113, paragraph 3(e)

UDI requirements in Great Britain

There are no specific requirements in the 2002 Medical Device Regulations regarding UDIs

Using the powers within the Medicines and Medical Devices Act 2021, MHRA look to improve the traceability of medical devices:

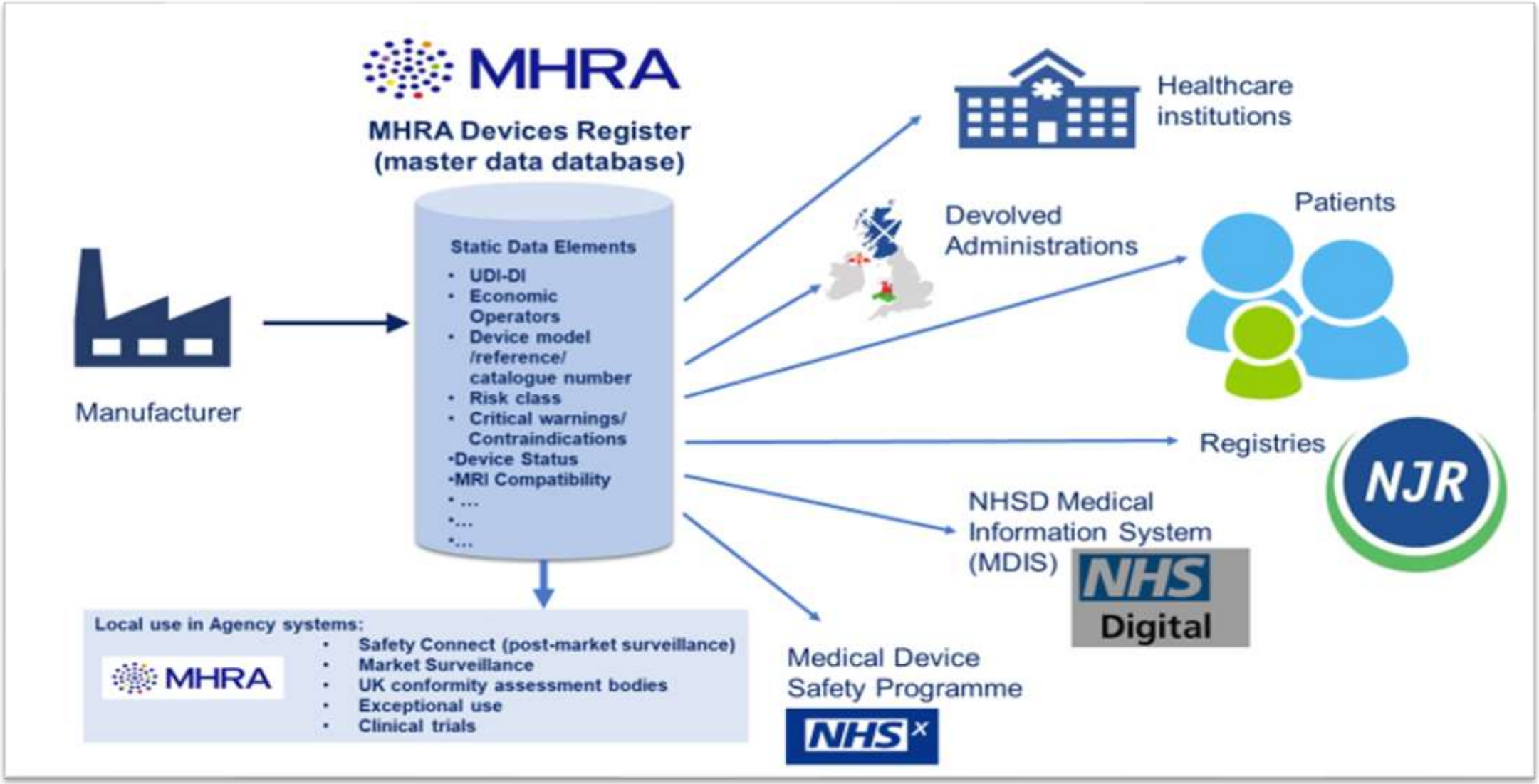
The MHRA Medical Devices Register will capture information (master data) about all medical devices available on the UK market.

(Will capture DIs only)

The NHSD Medical Devices Information System will facilitate the tracking of
k medical devices to a patient's individual record.

Collecting and storing information linking a UDI to patients, clinicians, and the specific surgical procedure where the device was implanted.

(Will capture DIs and PIs)


MHRA
MHRA Devices Register
(master data database)
Static Data Elements
• UDI-DI
• Economic Operators
• Device model /reference/ catalogue number
• Risk class
• Critical warnings/ Contraindications
•Device Status
•MRI Compatibility
• ...
•...
•...
Manufacturer
Healthcare institutions
Devolved Administrations
Patients
Registries
NJR
NHSD Medical Information System (MDIS)
NHS Digital
Medical Device Safety Programme
NHSX
Local use in Agency systems:
MHRA
• Safety Connect (post-market surveillance)
• Market Surveillance
• UK conformity assessment bodies
• Exceptional use
• Clinical trials

MHRA Devices Registration System

Medicines & Healthcare products Regulatory Agency

Registration of devices in Great Britain

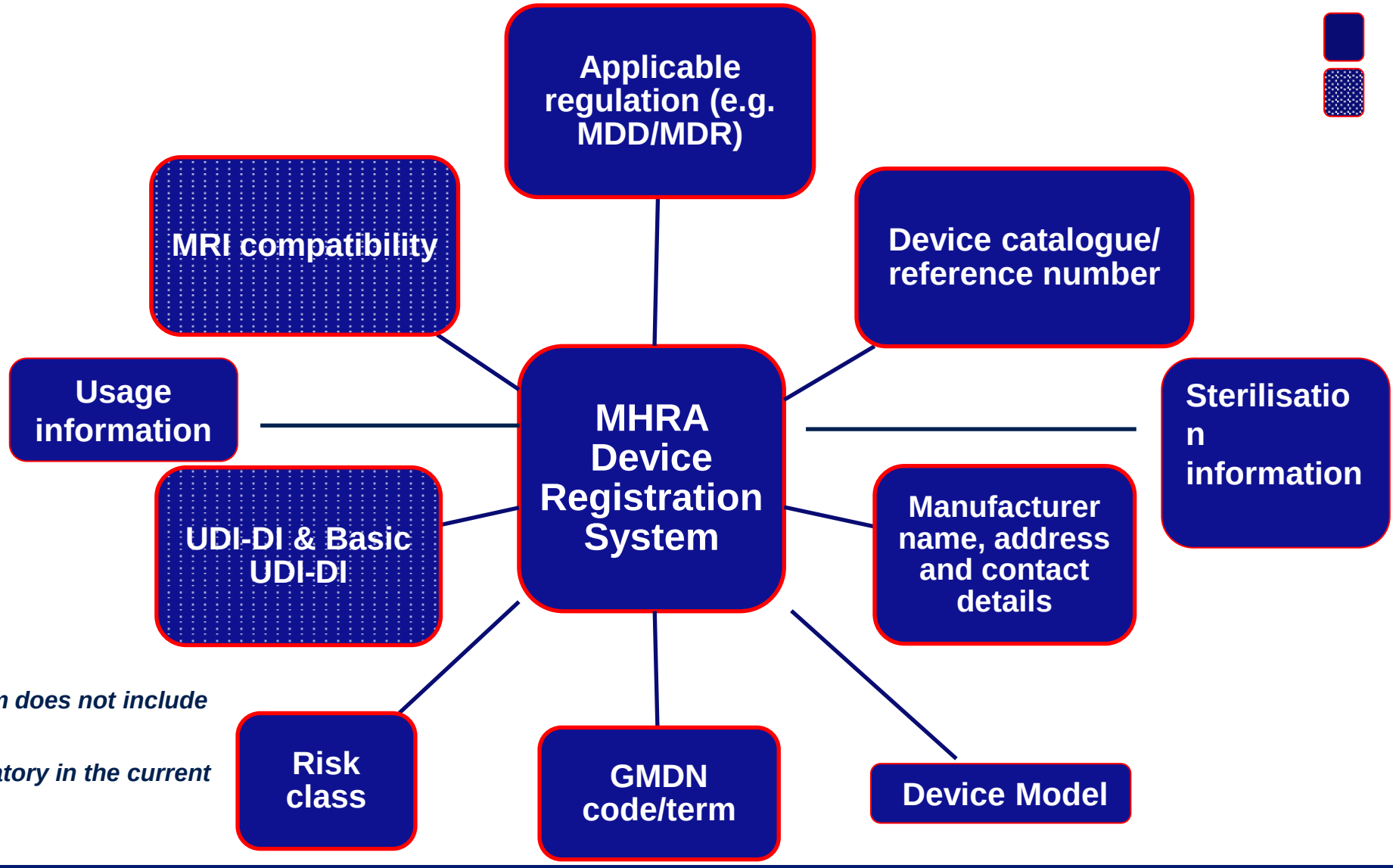
It is requirement of the UK MDR 2002 (as amended 2020) that devices are registered with the MHRA before they are placed on the market in GB

Registration from	Medical devices to be registered*	IVDs to be registered
1 May 2021	• Class III medical devices • Class IIb implantable medical devices • Active implantable medical devices	• IVD List A products
1 September 2021	• Class IIb non-implantable medical devices • Class IIa medical devices	• IVD List B products • Self-test IVDs
1 January 2022**	• Class I medical devices	• General IVDs

**Custom-made devices to be registered in line with the risk class of the device*

***Applies only to devices that are not already required to be registered*

Device Registration System fields



The Registration System does not include Production Identifiers

Not all Fields are mandatory in the current system

MHRA

UDI inclusion in safety communications

Medicines & Healthcare products Regulatory Agency

Using UDIs in Field Safety Corrective Actions and Recalls

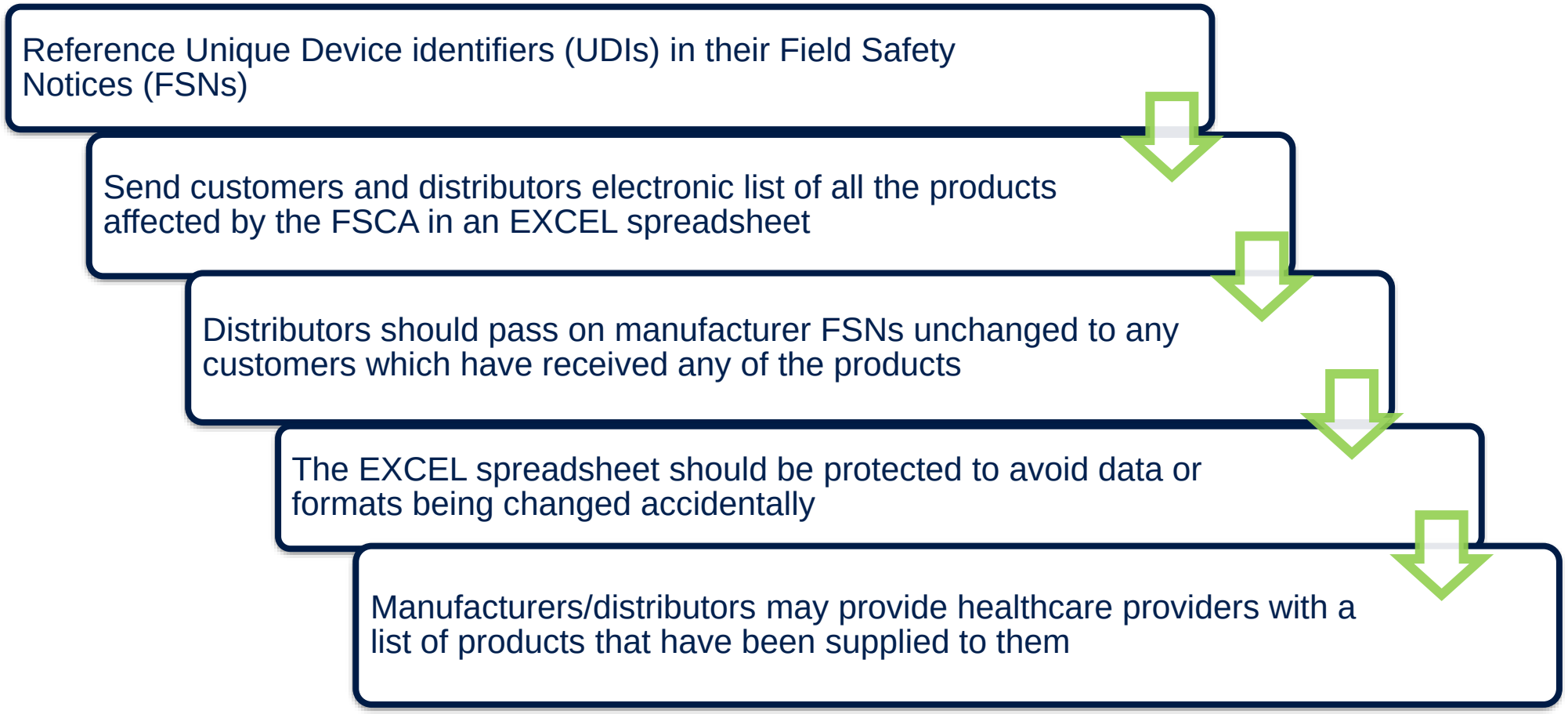
Manufacturers should:

- 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

Manufacturer requirements

Recommendations



Healthcare Providers guidance

Recommendations

GS1 UDI Device and Header Spreadsheet

Device Tab

Mandatory Items			Optional Items			
Device Identifier GTIN	**Catalogue Number (Manufacturer Product Code)**	**Product Description**	**Batch/Lot Number**	**Serial Number**	**Use-by Date**	**Date of Manufacture**

Tables notes:

- The GTIN should be prepended by zeros, if necessary, to make up to 14 digits.
- If all batches/serial numbers are affected, then columns D/E may be left blank.
- The use-by-date and date-of-manufacture should be formatted in excel date format and displayed as yy/mm/dd
- If there is any missing information, the cell should be left as a clear field.
- Any additional fields (i.e. NHS supply chain codes) should be added after the existing columns. The order of the columns should not be changed.

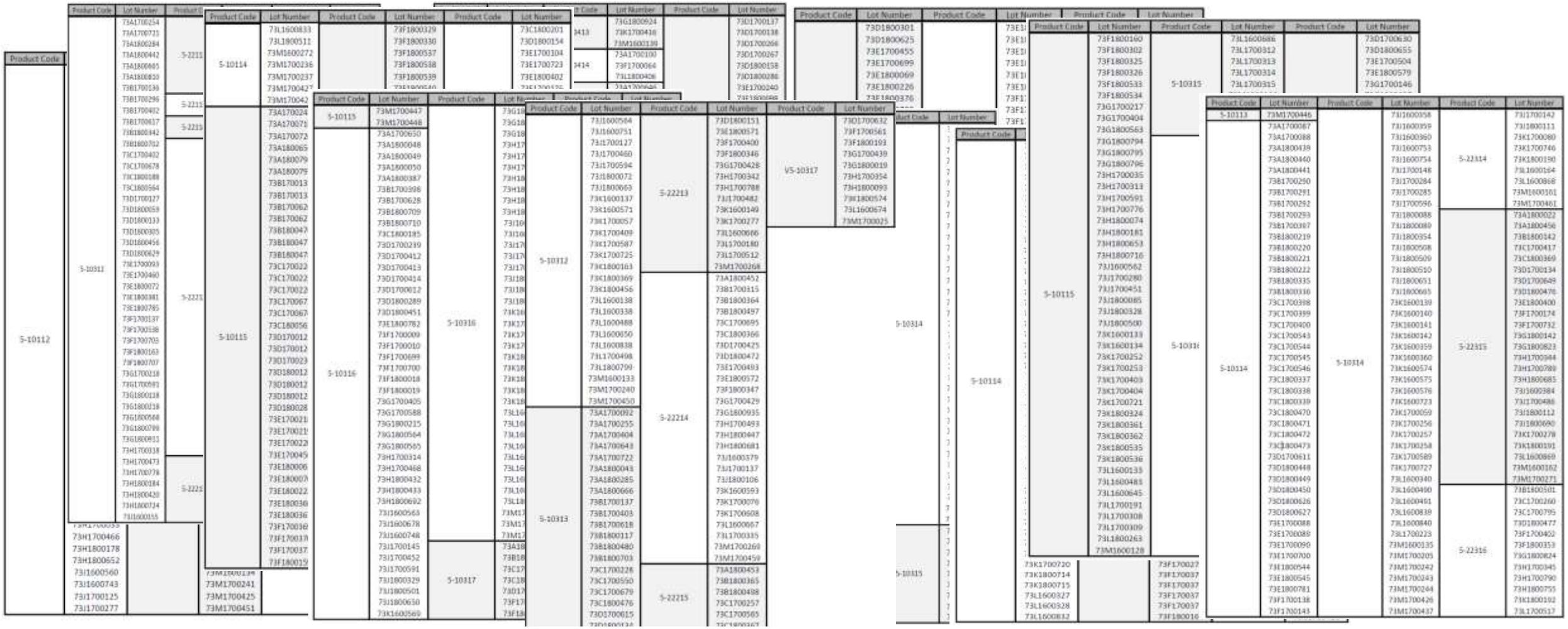
Header Tab

Single Registration Number (SRN) Reference	
Company Name	
***Company Global Location Number (GLN)**	
Company FSN Reference	
FSN Issue date	
*Company Global Location Numbers (GLNs) is a mandatory item. GLNs are used to identify legal entities such as companies. You may already know your GLN but if not contact you local GS1 Membership Organisation or GS1 UK at healthcare@gs1uk.org. If you are a distributor you also need to be identified using a GLN. Please contact GS1 UK at healthcare@gs1uk.org for more information.	

HIBCC UDI Device and Header Spreadsheet

Mandatory items (text format)			Optional items					
***Device Identifier (Variable Length, Minimum Character Length= 7, Maximum Character Length = 25)**	**Catalogue number (Manufacturer product code)**	**Product Description**	**Batch/Lot number**	**Serial number**	**Use-by date excel date format (yy/mm/dd)**	**Date of manufacture excel date format yy/mm/dd)**	Tables notes: •If all batches/serial numbers are affected, then columns D/E may be left blank. •The use-by-date and date-of-manufacture should be formatted in excel date format and displayed as yy/mm/dd •If there is any missing information, the cell should be left as a clear field. •Any additional fields (i.e. NHS supply chain codes) should be added after the existing columns. The order of the columns should not be changed.	*HIBCC Device Identifier Parameters: •All HIBCC Device Identifiers start with a "+", which is the HIBCC Flag Character •The four alphanumeric characters that follow the "+" are the Labeler Identification Code (LIC) or Company Prefix. •The Product/Catalog Code follow the LIC. The Product Catalog Code is alphanumeric and variable length (1-18 characters) •The Unit of Measure/Package Level Indicator follows the Product/Catalog Code. The Unit of Measure is a single numeric digit (0-9) •The last character in the Device Identifier is the Mod 43 Check Character •The HIBC standard allows for the Device Identifier and Production Identifier to be concatenated (combined in a single bar code). If the data is concatenated, the Check Character at the end of the Device Identifier will be removed and a new Check Character will be calculated at the end of the combined data string. The Device Identifier and Production Identifier will be separated by a "/" for concatenated data strings.

Extract from an FSN



Links to further information

Updated guidance on MHRA Devices Registration system was published on the gov.uk website on 31 December 2020 – see:

https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market

This includes details of information being collected – see *Manufacturer and Device and Product and Importer Attributes from 01 Jan 2021* spreadsheet:

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/949069/Manufacturer_and_Device_and_Product_and_Importer_Attributes.xlsx

https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk

Enquiries: devices.regulatory@mhra.gov.uk

Thank you

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