The new EU Medical Devices Regulations

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Contents

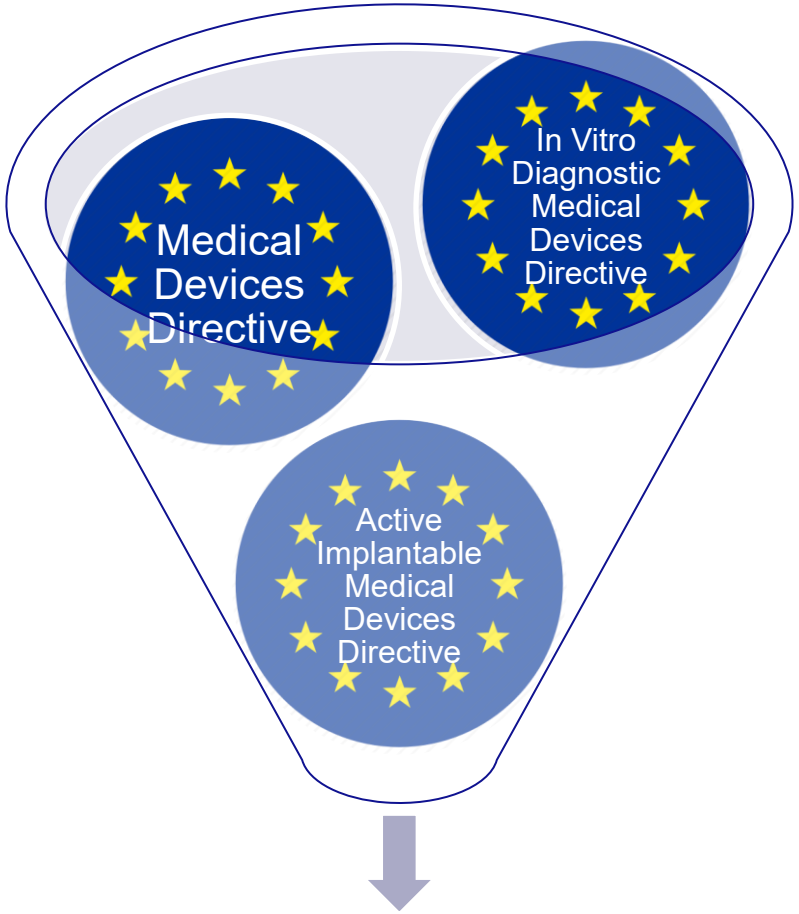
- Introduction to the Legislation
- Key Changes
- Timelines
- European Implementation
- Brexit
- Useful Links

2

The Legislation – why change it?

3

The Legislation – The Directives



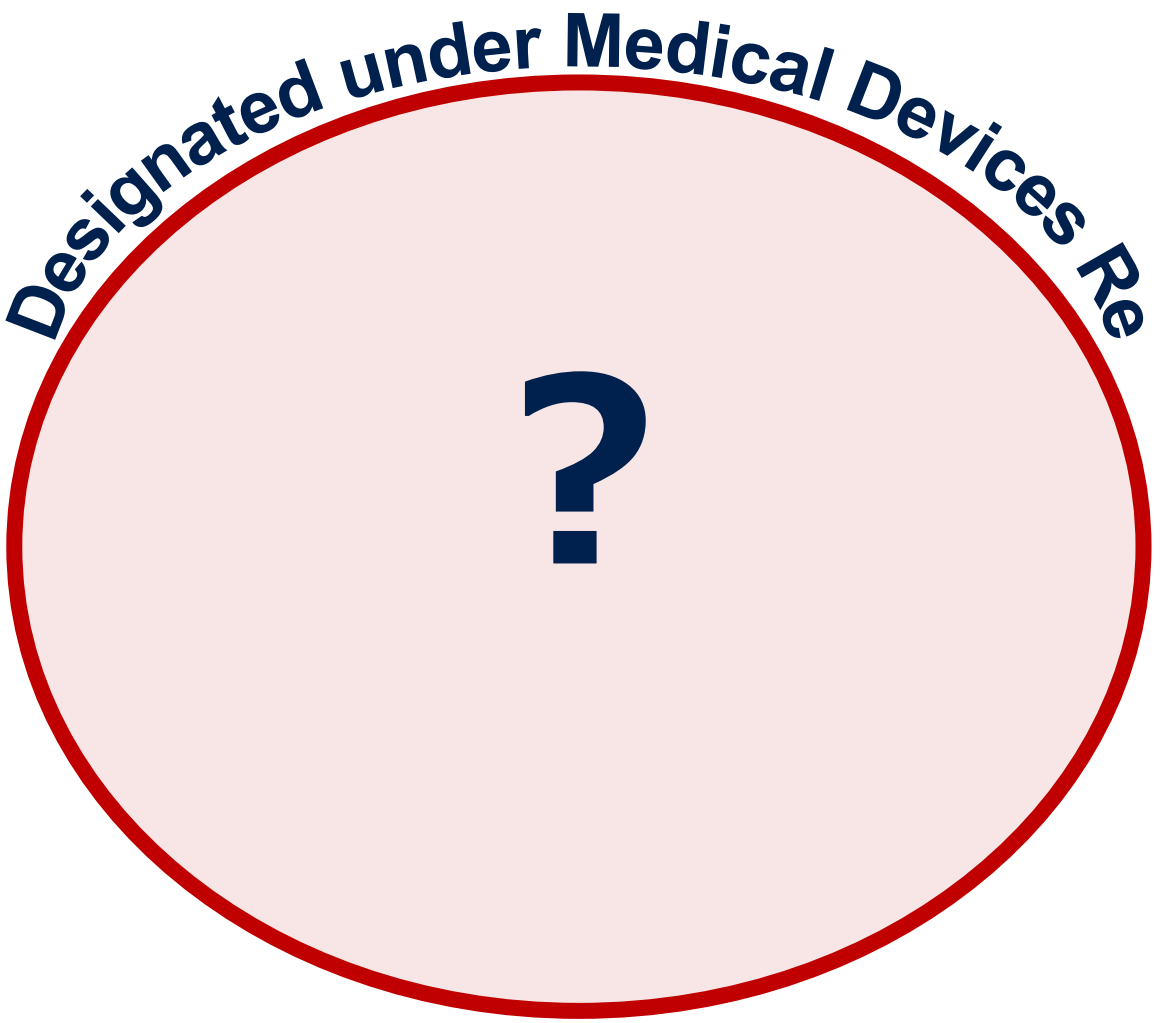
Medical Devices Regulations 2002

4

The Legislation – The Regulations

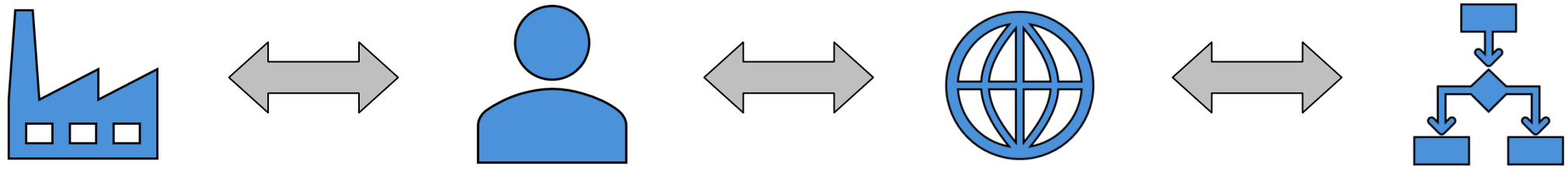
5

Notified Bodies



6

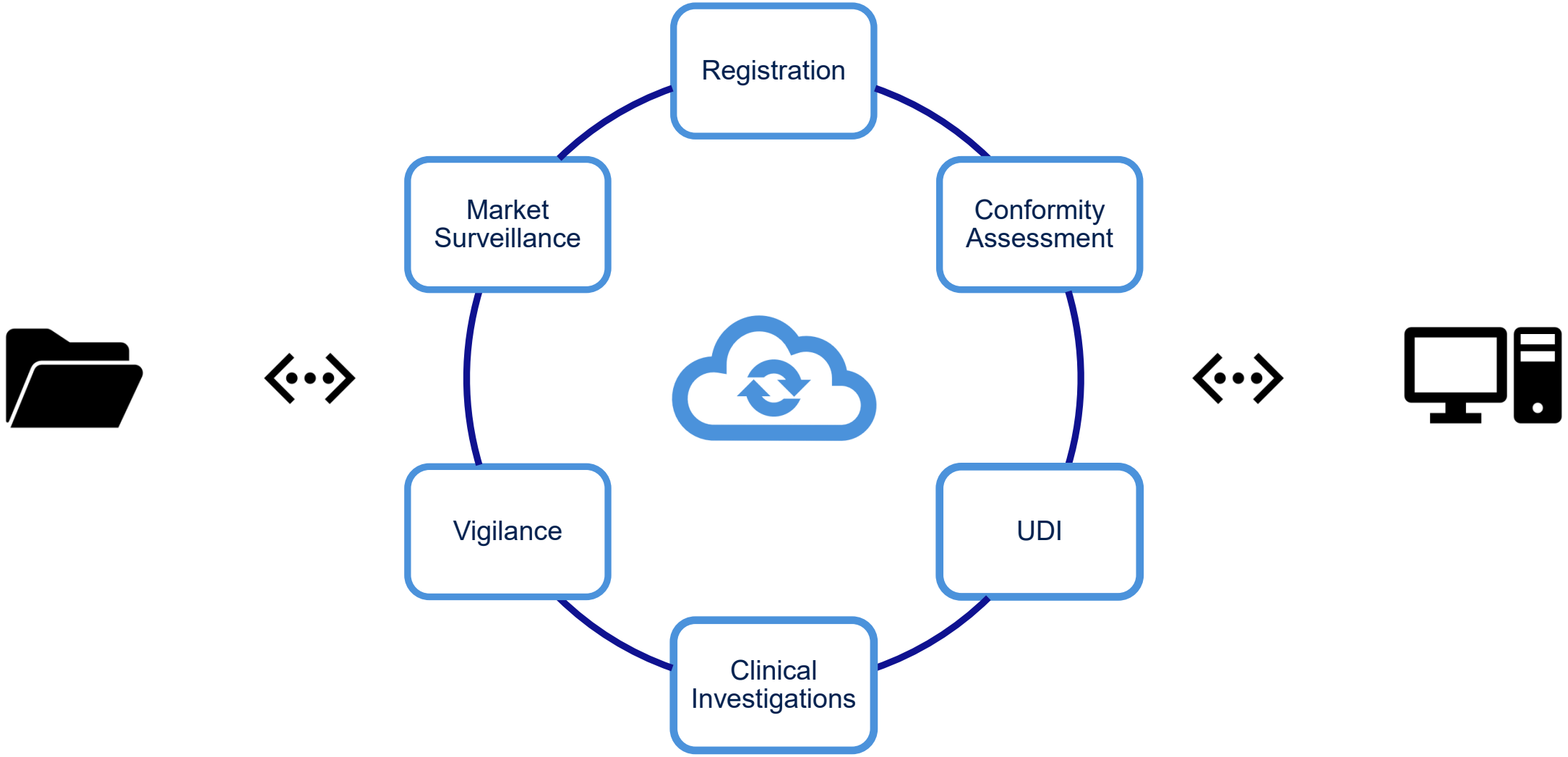
The Supply Chain



Manufacturer Obligations	Authorised Rep. Obligations	Importer Obligations	Distributor Obligations
Article 10	**Article 11**	**Article 13**	**Article 14**

7

Traceability - Eudamed



8

Traceability – UDI

Device Identifier:

(01) Device and manufacturer identification

Production Identifier:

(17) Expiry date

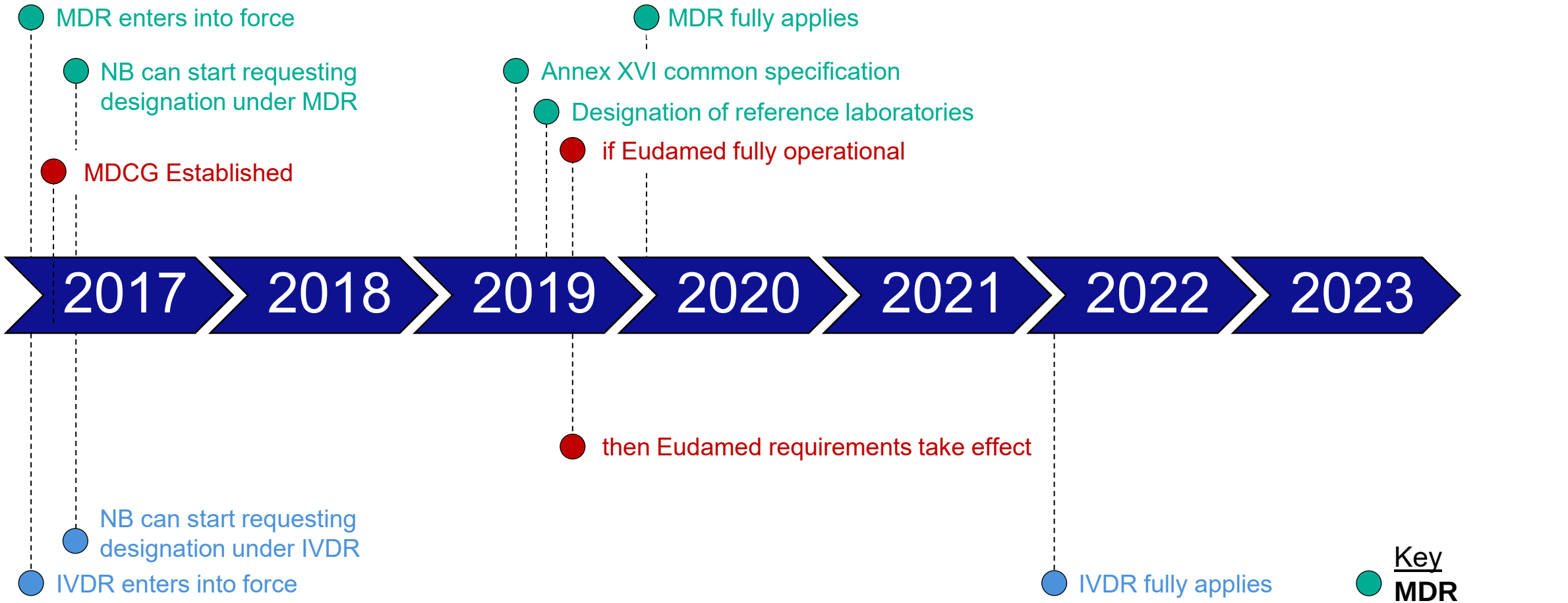
(10) Lot Number

(21) Serial Number

SCAN4SAFETY
Patient. Product. Place. Process.

9

Timelines



10

MDR Key Changes

2017

Reprocessing

2018

Active Implantable MD within MDR

2019

Unannounced manufacturer audits

2020

Increased req. for clinical evidence

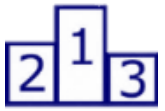
2021

Software MD may required notified body assessment

Scope to include products without a medical purpose

Scope to include devices with human cells

Notified body fees to be made public



Classification

Changes on claiming equivalence

Health Institution Exemption

“Joint Assessments” on Notified Bodies

Person Responsible for Regulatory Compliance

Incident reporting obligations

Competent authorities to publish annual market surveillance plan

11

Health Institutions and the New Regulations

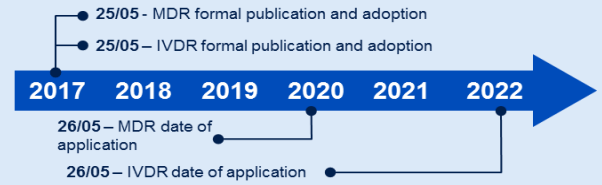
MHRA

Background

The new Medical Device Regulation (MDR) and the In Vitro Diagnostic Medical Device Regulation (IVDR) entered into force on 25 May 2017. Once fully applied, they will replace the medical device, in vitro diagnostic medical device and active implantable medical device Directives.

The new regulations include obligations that health institutions will need to meet by 26 May 2020 for medical devices and 26 May 2022 for in vitro diagnostic devices. Health institutions are defined as “an organisation the primary purpose of which is the care or treatment of patients or the promotion of public health” (Article 2(36) of the MDR).The key requirements are listed below, with more details included in Articles referenced.

Timeline



Current situation

The current EU medical device and in vitro diagnostic medical device Directives (MDD and IVDD) do not apply to devices manufactured and used only within the same health institution and on the premises of their manufacture or used on premises in the immediate vicinity without having been transferred to another legal entity (in-house use).

Therefore, under the Directives, devices manufactured and used within health institutions are not considered as having been put into service and health institutions are exempt from the obligations set out in the Directives.

Key changes set out in the MDR and IVDR

Health institution exemption (Article 5 of MDR / IVDR)

Devices that are manufactured or modified and used within health institutions shall be considered as having been put into service.

The requirements in the MDR/IVDR shall not apply to these devices provided that the certain conditions are met, including:

- Health institutions ensure that manufacturers follow the relevant general safety and performance requirements (Annex I);
- An appropriate quality management system is established;
- The health institution justifies that the target group’s specific needs cannot be met by an equivalent device on the market;
- Information is made available to competent authorities on request;
- A declaration with certain details is made publicly available;
- Reviews experience gained from clinical use of the devices and takes all necessary corrective actions.

Implant cards (Article 18 of MDR)

Health institutions will need to provide patients with implantable devices with an implant card, which shall bear the patient’s identity, as well as rapid access to certain information, including:

- The identification of the device, including the device name, serial number, lot number, the UDI, the device model, and the name, address and website of the manufacturer;
- Warnings, precautions or measures to be taken by the patient or a healthcare professional;
- The expected lifetime of the device and any necessary follow-up.

Unique Device Identification (Articles 27/24 of MDR/IVDR)

The UDI system will allow for things like safety alerts, potential recalls, as well as surveillance tasks more generally.

For Class III implantable medical devices, health institutions will need to store and keep preferably by electronic means the UDI of the devices which they have supplied or with which they have been supplied. Health institutions may be required to do this for other devices also.

The UDI system will have a longer phase-in time (e.g. the requirement applies for class III and implantable devices in May 2021 and class A IVDs in May 2027).

Other changes

Clinical trial / performance studies – Article 73 of MDR / Article 69 of IVDR: significant alignment with the CTR, for example introducing damage compensation and a ‘Sponsor’.

Single-use devices and their reprocessing – Article 17 of MDR: may only take place where permitted by national law, but must meet certain conditions. The MHRA will consult on its current position on reprocessing.

3D printed devices – a case-by case assessment will be required to determine a product’s status and classification.

Software – classification rules will change with more software requiring notified body input.

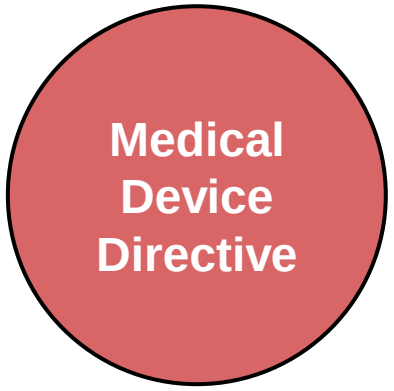
12

Health Institution Exemption

NOW

Medical devices manufactured within a health institution and used on patients within that same health institution are exempt from complying to the Medical Devices Regulations 2002.

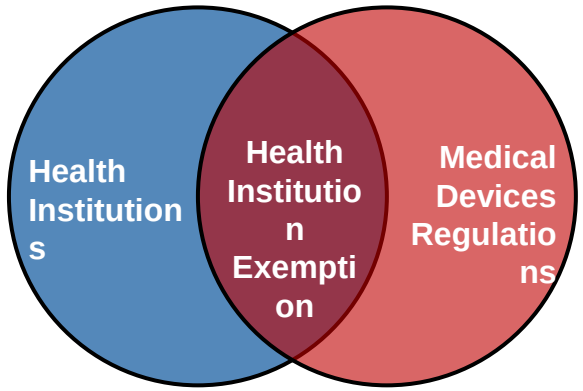
Currently, health institutions are not within the scope of the Medical Devices Directive and the Active Implantable Devices Directive.



MDR/IVDR

Medical devices manufactured or modified and used within a health institution will need to comply with specific requirements set out in Article 5.5 of the Medical Devices Regulation 2017/745 and the In Vitro Medical Devices Regulation 2017/746.

In the new regulations, health institutions will now fall within the scope of the regulation.



13

Annex XVI

- Do not have a medical purpose
- Are usually cosmetic/aesthetic products that would be regulated as medical devices under the MDR
- Will be required to comply with safety and performance requirements based on Common Specifications
- Not automatically class I devices – **notified body involvement** may be required

14

Annex XVI in more detail

1. **Contact lenses** or **other items** intended to be introduced **into or onto the eye**.

2. Products intended to be **totally or partially introduced into the human body through surgically invasive means** for the purpose of **modifying the anatomy or fixation of body parts** with the **exception of tattooing products and piercings**.

3. **Substances**, combinations of substances, or **items** intended to be used **for facial or other dermal or mucous membrane filling** by subcutaneous, submucous or intradermal **injection** or **other introduction**, **excluding** those for **tattooing**.

15

Annex XVI in more detail

4. **Equipment** intended to be used to **reduce, remove or destroy adipose tissue**, such as equipment for liposuction, lipolysis or lipoplasty.

5. **High intensity electromagnetic radiation** (e.g. infra-red, visible light and ultra-violet) **emitting equipment** intended for use on the human body, **including coherent and non-coherent sources, monochromatic and broad spectrum**, such as lasers and intense pulsed light equipment, **for skin resurfacing, tattoo or hair removal or other skin treatment**.

6. **Equipment i**ntended for brain stimulation that **apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain**.

16

Implementation Progress

COEN
- Bringing 'PRRC' paper to group
- Contributing to market surveillance strategy

NBOG
- Training sessions on CAPA and process for designation
- Resource and IVDR requirements

IVD WG
- Creation of an operational implementation plan: classification, performance evaluation and companion diagnostics

Vigilance WG
- Development of PSUR guidance

Communications
- Introductory guide
- Stakeholder-specific leaflets

Health institutions
- New guidance being drafted based on consultation

Notified Bodies
- BSI designated under MDR Jan 2019

Market surveillance
- BEIS Market Surveillance Coordination Committee

Reprocessing SUDs
- Drafting consultation

Registrations
- Updating internal databases for new Regulations
- Now accepting class 1 under MDR/IVDR

Software WG
- Consensus around Rule 11 up-classification

CIE WG
- Developing equivalence guidance

TSG
- Transition FAQ documents

CAMD
- Members of Executive Group

ITF
- Implementation roadmap
- Stakeholder enquiry form

BCWG
- Reviewing key definitions
- Updating MEDDEV guidance
- Off-label use of medicinal products (Rule 13)
- Level 3 requirements for brain stimulation products under Annex XVI

Eudamed
- Cross-cutting Eudamed subgroups

IMDRF International Medical Device Regulators Forum

- Custom-made devices
- MDSAP
- Good regulatory review practices
- Registries WG
- Medical Device Adverse Event Terminology

17

Competent Authorities for Medical Devices (CAMD) Implementation Roadmap

18

Transition Subgroup

Frequently Asked Questions Documents for MDR/IVDR Transitional Provisions

- Addressing 10 issues
- Answering 42 questions

19

Key messages

- MDR will apply by **25 May 2020**
- IVDR will apply by **25 May 2022**
- Check it is CE marked under MDR/IVDR
- Assign UDI as per transition provisions
- Provide implant cards
- MHRA's Yellow Card Scheme

Brexit

21

Useful links

CAMD Implementation Roadmap: https://www.camd-europe.eu/regulatory/medical-devices-regulation-vitro-diagnostics-regulation-mdr-ivdr-roadmap/

Transition FAQs: https://www.camd-europe.eu/regulatory/available-now-mdr-ivdr-transitional-faqs/

MHRA's introductory guide to the EUDR: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/640404/MDR_IVDR_guidance_Print_13.pdf

MHRA's EUDR guidance page: www.gov.uk/guidance/medical-devices-eu-regulations-for-mdr-and-ivdr

MHRA's consultation on health institution guidance: https://www.gov.uk/government/consultations/health-institution-exemption-for-ivdrmdr

NHS Confederation Briefing: http://www.nhsconfed.org/-/media/Confederation/Files/public-access/European-Office/EU-briefing-24-Medical-devices_2018_Final.pdf?la=en&hash=795CCABA01EAAE1F463D7F0474331E01E50A89FE

Yellow Card Scheme: https://yellowcard.mhra.gov.uk/

Brexit: https://www.gov.uk/government/collections/mhra-guidance-and-publications-on-a-possible-no-deal-scenario

Thank You

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