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Navigating the Landscape of EU MDR & IVDR: Implementation, Challenges, and Innovations

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Meet the Speakers

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About the Session

What you will learn:

- Why did the EU publish these new regulations?
- What are the UDI Requirements and what are they intended to achieve?
- What is EUDAMED?
- What are the requirements for different stakeholders – manufacturers, imports, authorized reps, distributors, healthcare facilities?
- What are the timelines for implementation?
- How this affects the UK and Switzerland?

Whereas: (41/38) The *traceability of devices* by means of a Unique Device Identification (UDI) system … should significantly enhance the effectiveness of the *post-market safety-related activities* for devices, which is owing to *improved incident reporting*, *targeted field safety corrective actions* and *better monitoring by competent authorities*. It should also help to *reduce medical errors* and to *fight against falsified devices*. Use of the UDI system should also improve purchasing and waste disposal policies and stock-management by health institutions and other economic operators and, where possible, be compatible with other authentication systems already in place in those settings.

Panel Questions

1. Why did the EU publish these new regulations?
2. What are the UDI Requirements and what are they intended to achieve?
3. What is EUDAMED?
4. What are the requirements for different stakeholders – manufacturers, imports, authorized reps, distributors, healthcare facilities?
5. What are the timelines for implementation?

Whereas:

(1) [The MDD, AIMD, IVDD] constitute the Union regulatory framework for medical devices… However, a fundamental revision of those Directives is needed to establish a robust, transparent, predictable and sustainable regulatory framework … which ensures a high level of safety and health whilst supporting innovation.

(2) …. this Regulation sets high standards of quality and safety for medical devices in order to meet common safety concerns … [and] harmonises the rules for the placing on the market and putting into service of medical devices and their accessories on the Union market thus allowing them to benefit from the principle of free movement of goods…

The new Medical Devices Regulation (EU) 2017/745 (MDR) and the In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR) bring EU legislation into line with technical advances, changes in medical science and progress in law-making.

The new regulations create a robust, transparent, and sustainable regulatory framework, recognised internationally, improving clinical safety and creating fair market access for manufacturers and healthcare professionals.

Unlike directives, regulations do not need to be transposed into national law. The MDR and the IVDR will therefore limit interpretation discrepancies across the EU market.

Benefits/Needs of the EU UDI Systems

The EU Unique Device Identification (UDI) System will:

1. Provide for the traceability of devices
2. Enhance the effectiveness of post-market safety-related activities
3. Improve incident reporting
4. Provide for targeted field safety corrective actions
5. Provide for better monitoring by competent authorities
6. Reduce medical errors
7. Fight against falsified devices
8. Improve purchasing, waste disposal policies and stock-management by health institutions

UDI General Rule – Place a UDI on the LABEL

1. The *LABEL* of EVERY medical device (including all IVDs) must have a UDI.
2. EVERY device package (contains a fixed quantity of a version or model) must have a UDI.

Any other approach is an exception to, or alternative from, these requirements.

US: Section 201(k) defines 'label' as a display of written, printed, or graphic matter upon the immediate container of any article...
EU: ‘label’ means the written, printed or graphic information appearing either on the device itself, or on the packaging of each unit or on the packaging of multiple devices;

What is a Medical Device…?

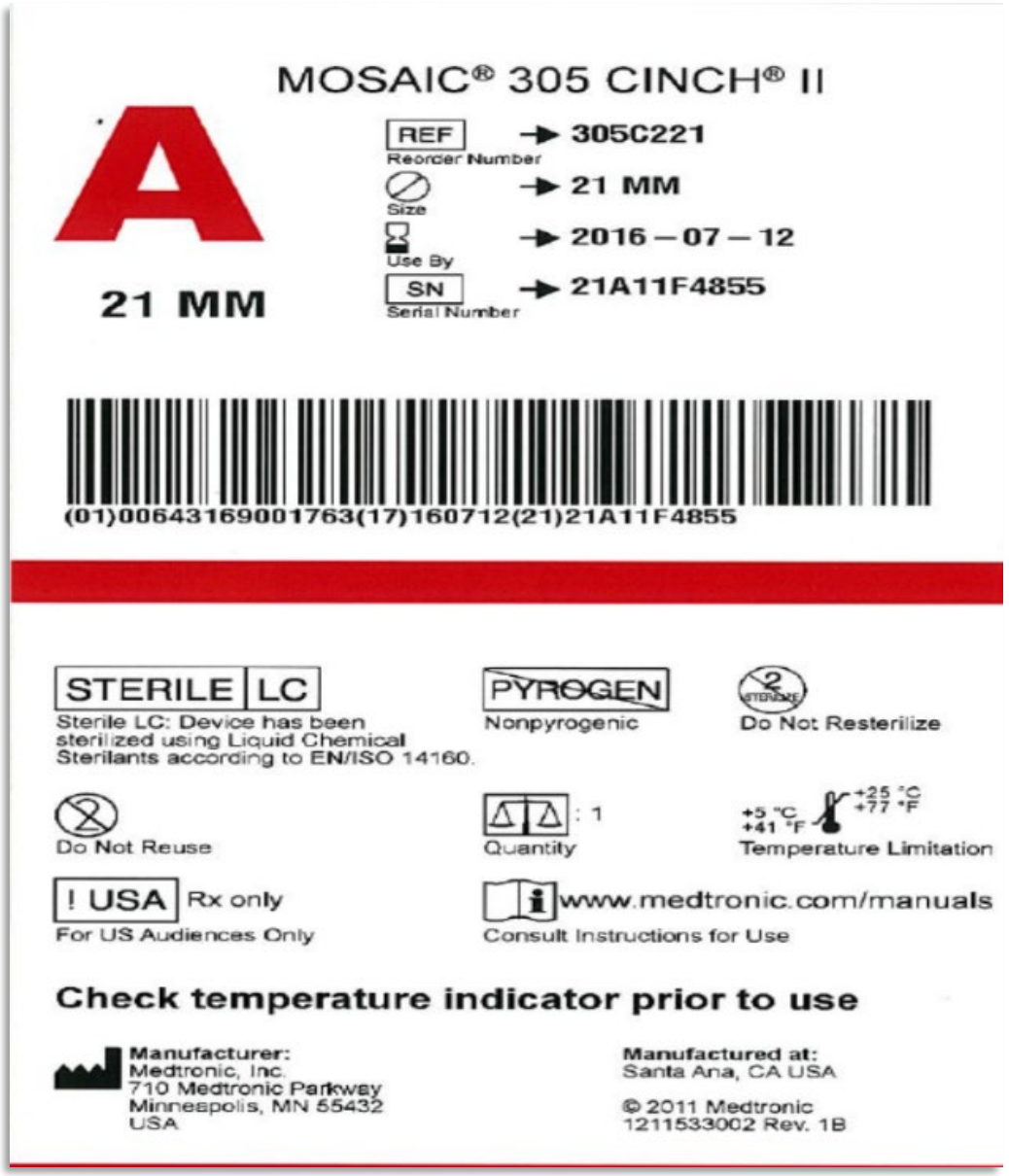
A device is … "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is… intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals….”

Direct Marking (DM – not DPM – UDI)

In addition to the label requirement – a “permanent marking” UDI is required on the device itself if:

Need to understand the difference between the UDI Label and the Direct Marking requirement!

Example



Barcode Verification

Verification: A technical measurement process to confirm that a barcode conforms to the applicable ISO symbol specifications.

Verifier: The tool used to make technical measurements.

- Measures the symbols vs. standards
- Calculates a Grade for the symbol
- Creates an Assessment Report
- Minimum grade is usually ‘C’ or better

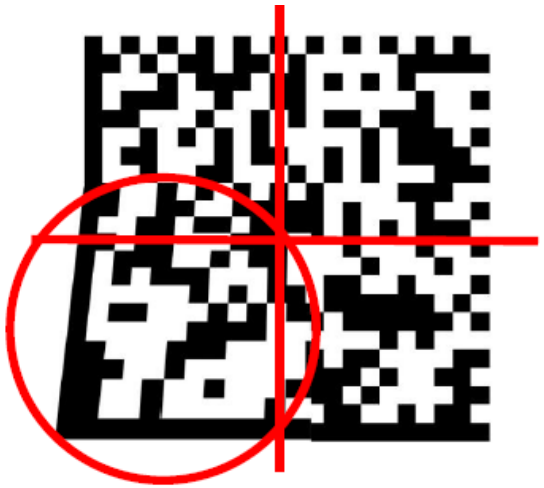


Figure 11 GS1 DataMatrix with poor Grid Non-uniformity

Identification in the Supply Chain

Economic operators (the manufacturer, authorized representative, importer, distributor, and system or procedure pack producers or sterilizers) *must keep* (*preferably by electronic means*), the UDI of these devices that they have BOTH supplied and been supplied with:

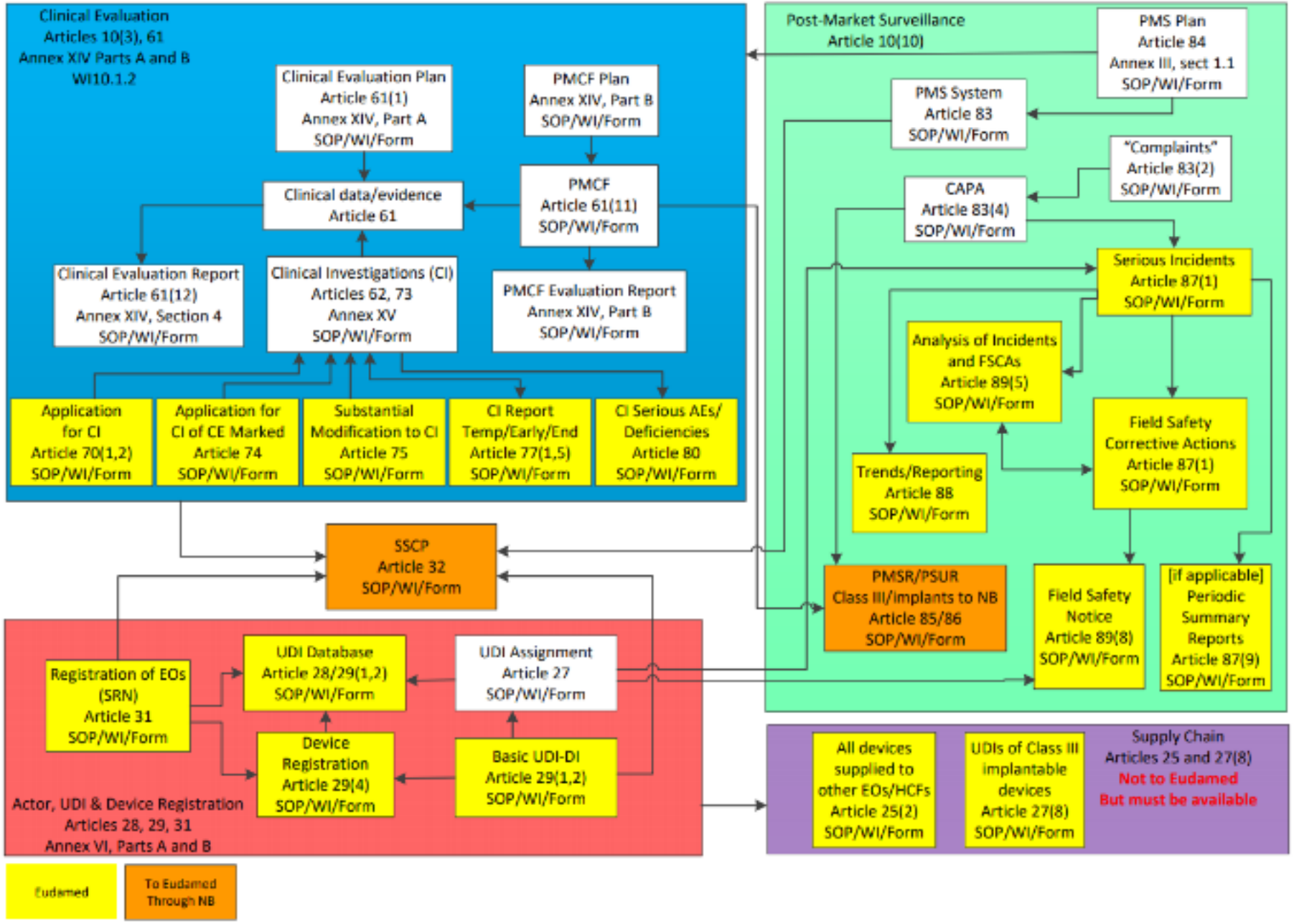
- Class III implantable devices, and
- Other devices the EC adopts through delegated acts.

Health institutions *must keep* (*preferably by electronic means*) the UDI of:

- Class III implantable devices, and
- Others devices added by member states.

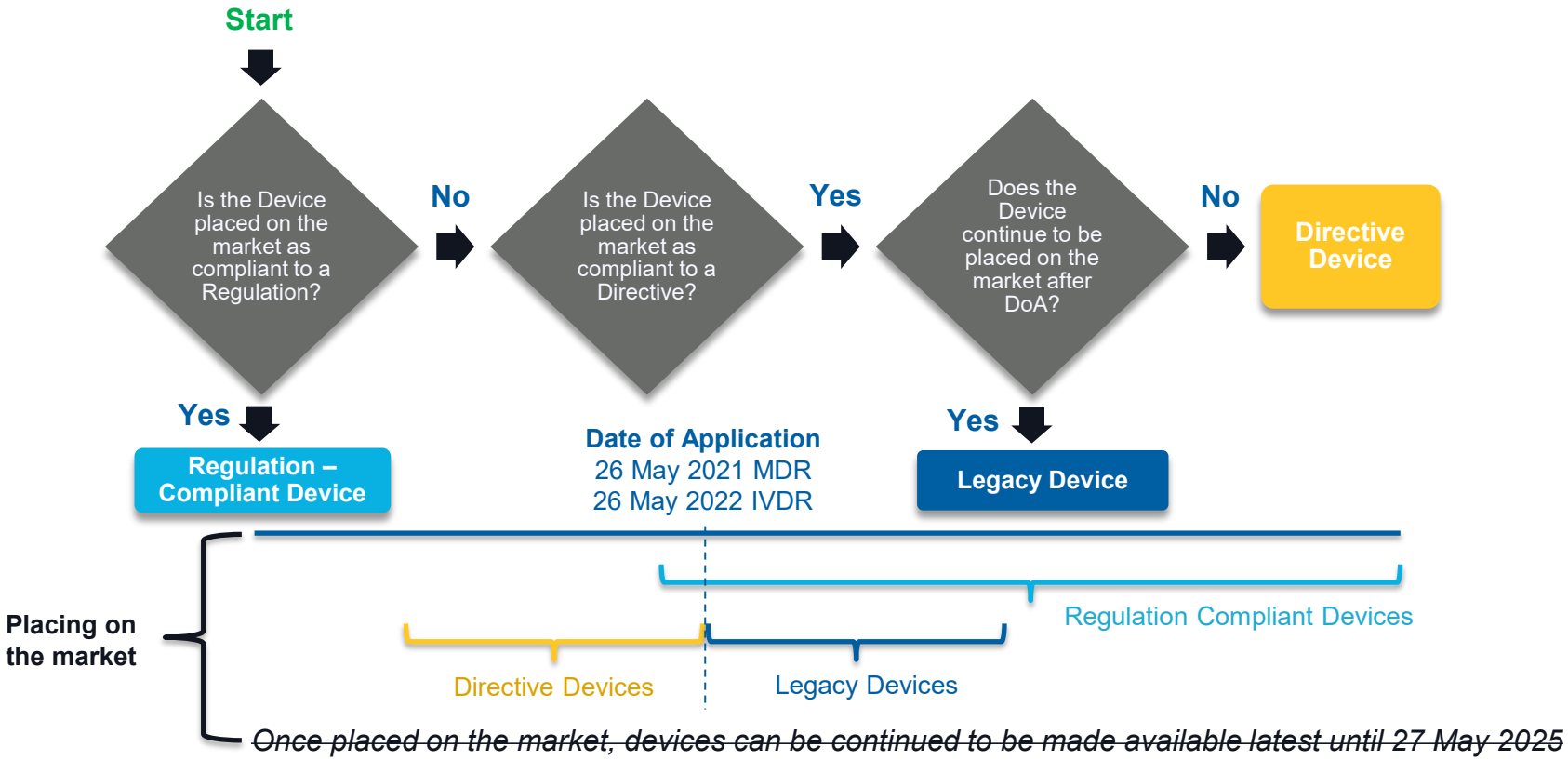
Flow of information

MDR EUDAMED Flowchart + Add Client SOPs, WIs, and/or Forms



USDM Life Sciences

EU Regulations – MDR and IVDR

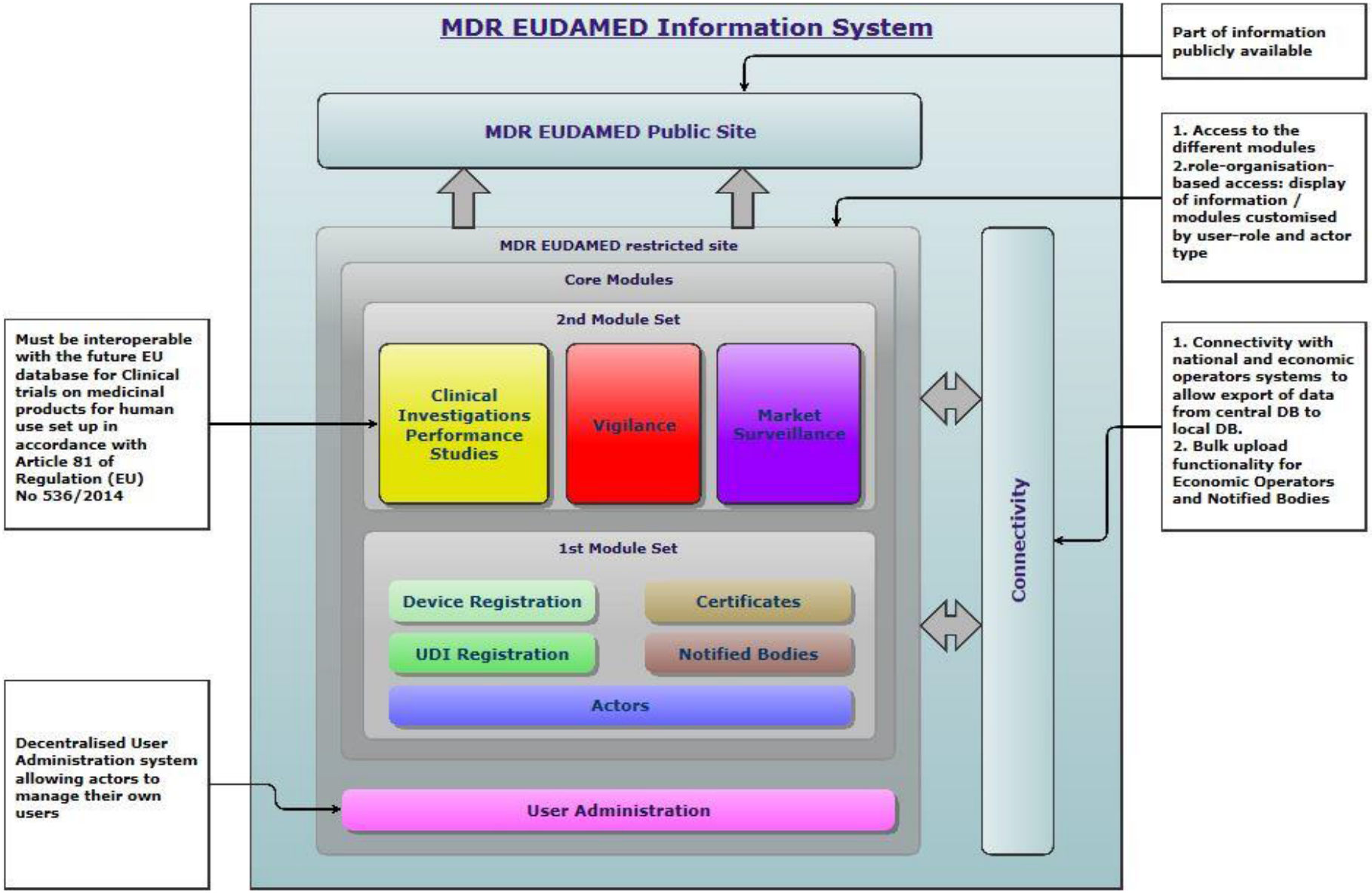


EUDAMED is Vital to MDR/IVDR

(44/41) One key aspect in fulfilling the objectives of this Regulation is the creation of a European database on medical devices (EUDAMED) that should integrate different electronic systems to collate and process information regarding:

- devices on the market and
- the relevant economic operators,
- certain aspects of conformity assessment,
- notified bodies,
- certificates,
- clinical investigations,
- vigilance and
- market surveillance.

From: Draft Functional Specifications for EUDAMED



MedTech Europe's estimated timelines for EUDAMED completion and launch

EUDAMED Functionality Steps

[1] *EUDAMED Minimum Viable Product (MVP) means that the system developed implements the Medical Devices Regulations requirements and allows competent authorities and all stakeholders to comply with their legal obligations.*

European Commission

Questions & Comments

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THANK YOU!