MedTech Europe
from diagnosis to cure

Health Care Without Harm

EU Medical Devices Regulation 2017/745: implementation and EUDAMED for safer medical devices

27 September 2022

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About MedTech Europe

The European trade association for the medical technology industry including diagnostics, medical devices and digital health.

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from diagnosis to cure

OUR MEMBERS

140+ multinational corporations*

50 medical technology associations

*medical devices, diagnostics and digital health

About medical technology

Medical technology is any technology used to **save** and **improve** lives of individuals suffering from a wide range of conditions.

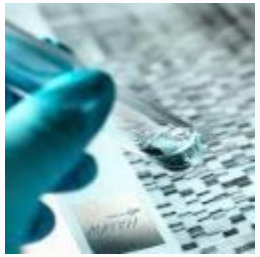
There are more than 500,000 products, services and solutions currently available


















Medical Devices Regulation in Brief

Former Directives (1990s)

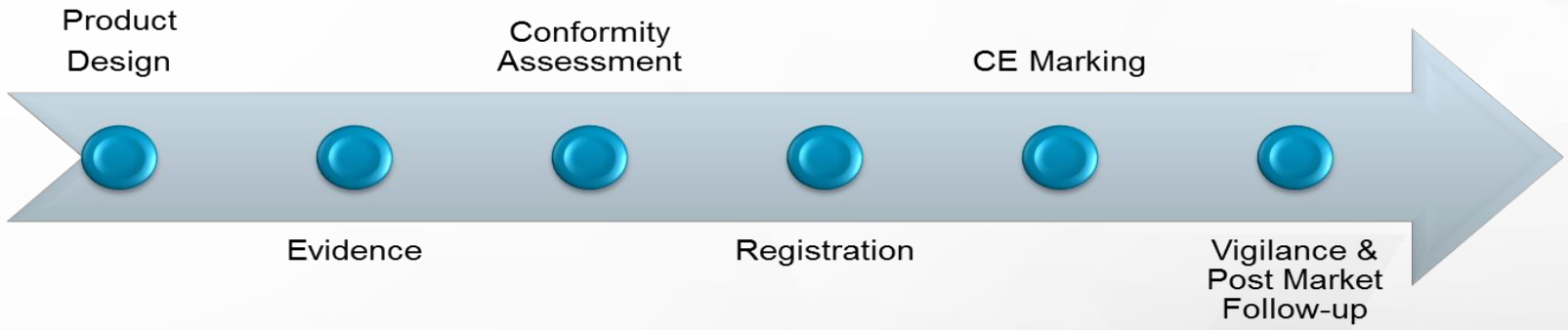
1. MDD: Medical Devices Directive 93/42/EEC
2. AIMDD: Active Implantable Medical Devices Directive 90/385/EEC

New Regulation (2017)

MDR: Medical Devices Regulation (EU) 2017/745

- *Note*: Dedicated rules on chemical substances are in MDR Annex I

High-level overview of the regulatory process:



A Modernised, Strengthened System

High-risk Devices

- **Up-classification:** Certain medical devices – e.g., joint or spinal disc replacements – are moved into the highest risk class
- **Expert panels**: Consulted on the clinical evaluation of innovative high-risk devices

Notified Bodies

- **Stricter:** Especially on clinical evidence of device safety and performance
- **Availability**: Concerns over timing and capacity ahead of the compliance deadlines

Clinical Evidence

- **Clinical data**: Strengthened obligations regarding data transparency and when new clinical investigations are / are not needed
- **Clinical investigations**: Dedicated EU rules

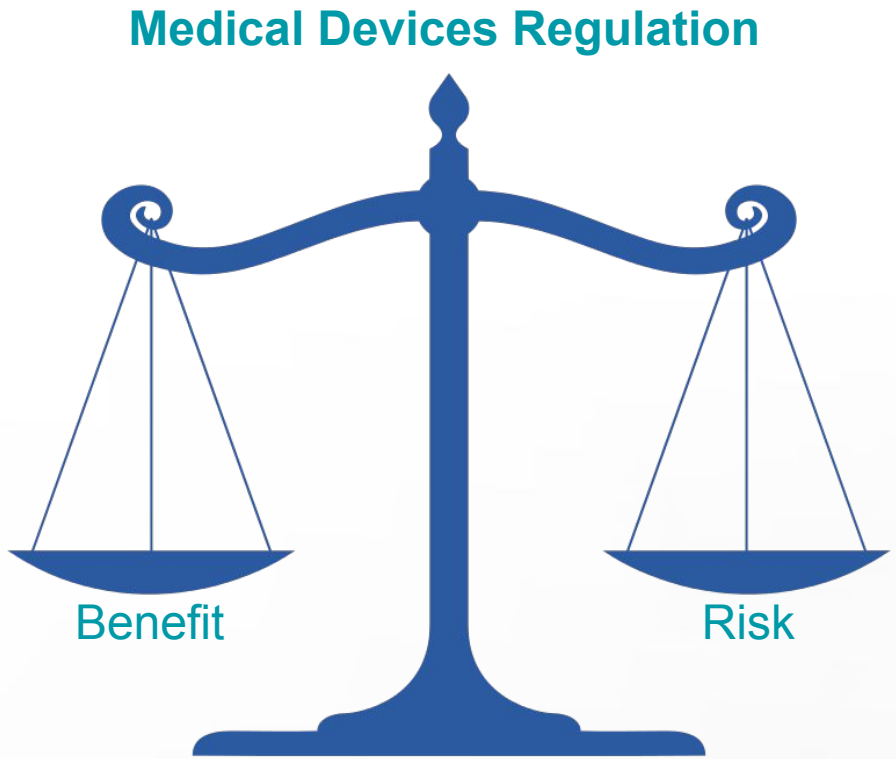
…and many more

- **Eudamed database**: Central EU databank for data submission and data transparency
- **Documentation**: Stricter requirements
- **Single-use devices**: Reprocessing regulated

Regulation of Chemicals in Medical Devices

CLP	REACH	RoHS	*MDR*
→ Hazard identification → *tool for next step in risk management* → *does not consider the context of use*	→*Horizontal legislation for all chemicals management* → *dynamic tool for risk management options* → *primary tool for driving safe management and substitution of chemicals*	→ *Restriction – with exemptions – to address risk at the waste stage* → *Waste legislation / limited scope (EEE / substances targeted)*	→ *Benefit-risk to patient assessment* → *Reduce the risk of release of substances from devices* → *For certain devices: CMR 1A/1B & endocrine disruptors only present above 0.1% if and disclosed via the device label and Eudamed*

Managing Chemical Risks via the MDR



- Benefit–risk determination (***for patient safety***) assessment in support of Annex I requirements on substances
- **Guidelines** have been developed by the *Scientific Committee on Health, Environmental and Emerging Risks* (SCHEER) for targeted substances and medical devices

EUDAMED implementation roadmap

Official timelines posted on the Commission website:

one additional year postponement announced (published in July 2022):

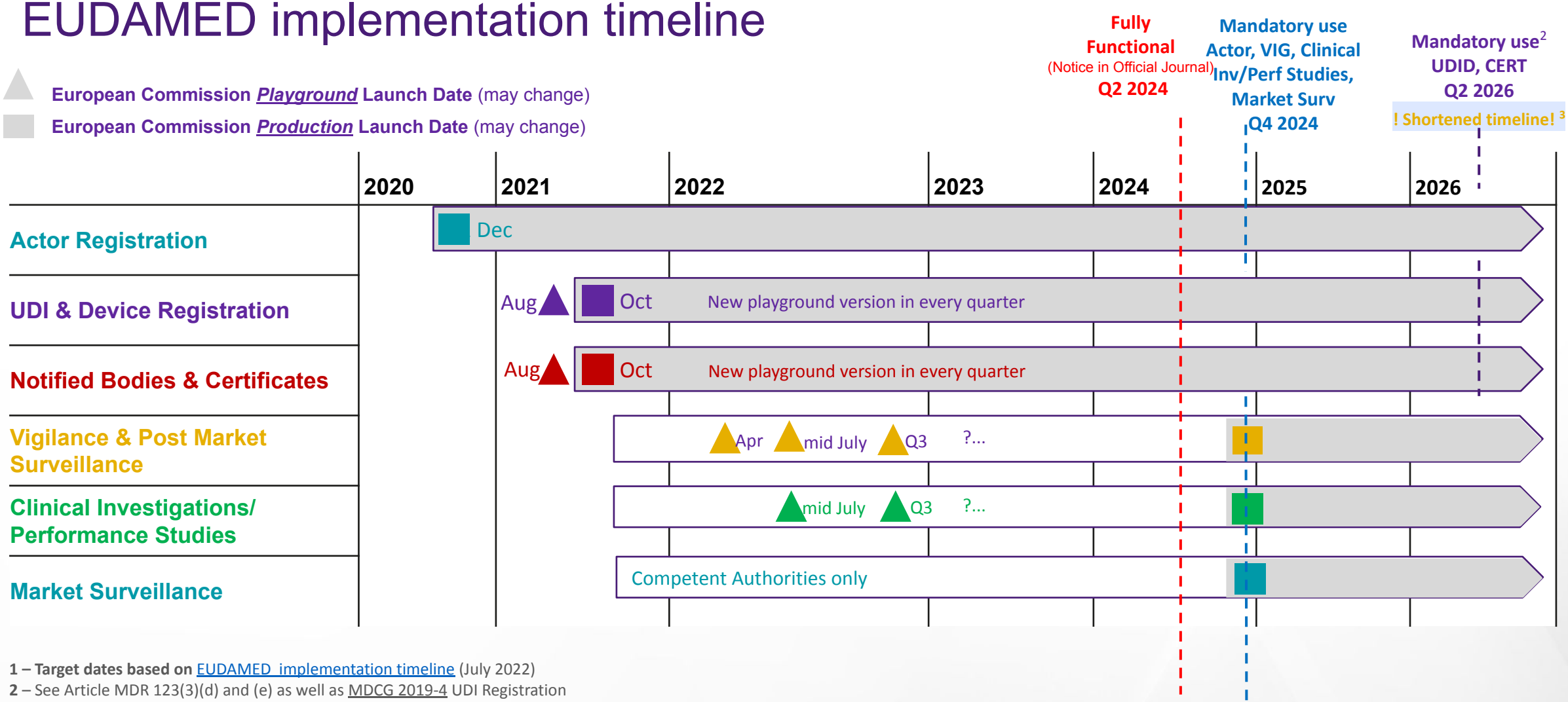
The European Commission planning – June 2022

Q4 2023	Q1-Q2 2024	Q2 2024	Q2 2024	Q4 2024	Q2 2026
End of the EUDAMED MVP[1] development for all six modules	Independent **Audit**	Audit results presented to the Medical Devices Coordination Group (MDCG)	EUDAMED has achieved full functionality following the outcome of the Audit. **Publication of a Commission notice** in the *Official Journal of the European Union* **(OJEU)** The full EUDAMED system (all 6 modules) is released.	End of 6 months transitional period after publication of the notice in the OJEU The use of **EUDAMED** becomes **mandatory** as regards obligations and requirements related to **Actors, Vigilance, Clinical Investigation & Performance Studies and Market Surveillance modules**	End of 24 months transitional period after publication of the notice in the OJEU The use of **EUDAMED** becomes **mandatory** as regards obligations and requirements related to **UDI/Device and NB & Certificate modules**

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

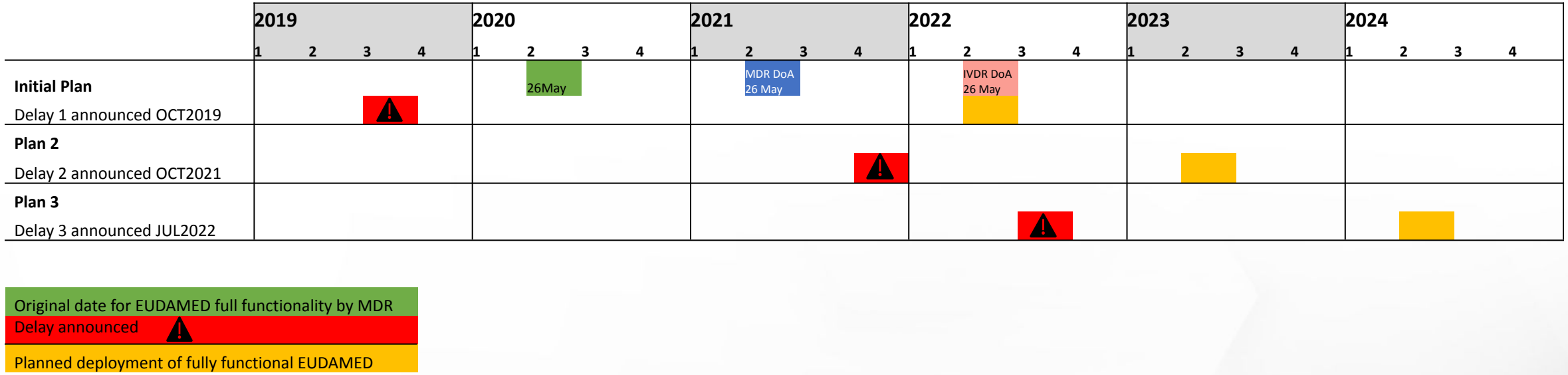
https://health.ec.europa.eu/system/files/2022-07/md_eudamed_timeline_en.pdf

EUDAMED implementation timeline



1 – Target dates based on EUDAMED implementation timeline (July 2022)
2 – See Article MDR 123(3)(d) and (e) as well as MDCG 2019-4 UDI Registration compliance date is 18 months later
3 - MDCG 2019-5 in case of a serious incident report and/or a field safety corrective action (with the field safety notice) to be reported during the 18-month transition timeline, devices must be registered *(+ PSUR, Trend report...)*

EUDAMED delay history



Original date for EUDAMED full functionality by MDR

Delay announced

Planned deployment of fully functional EUDAMED

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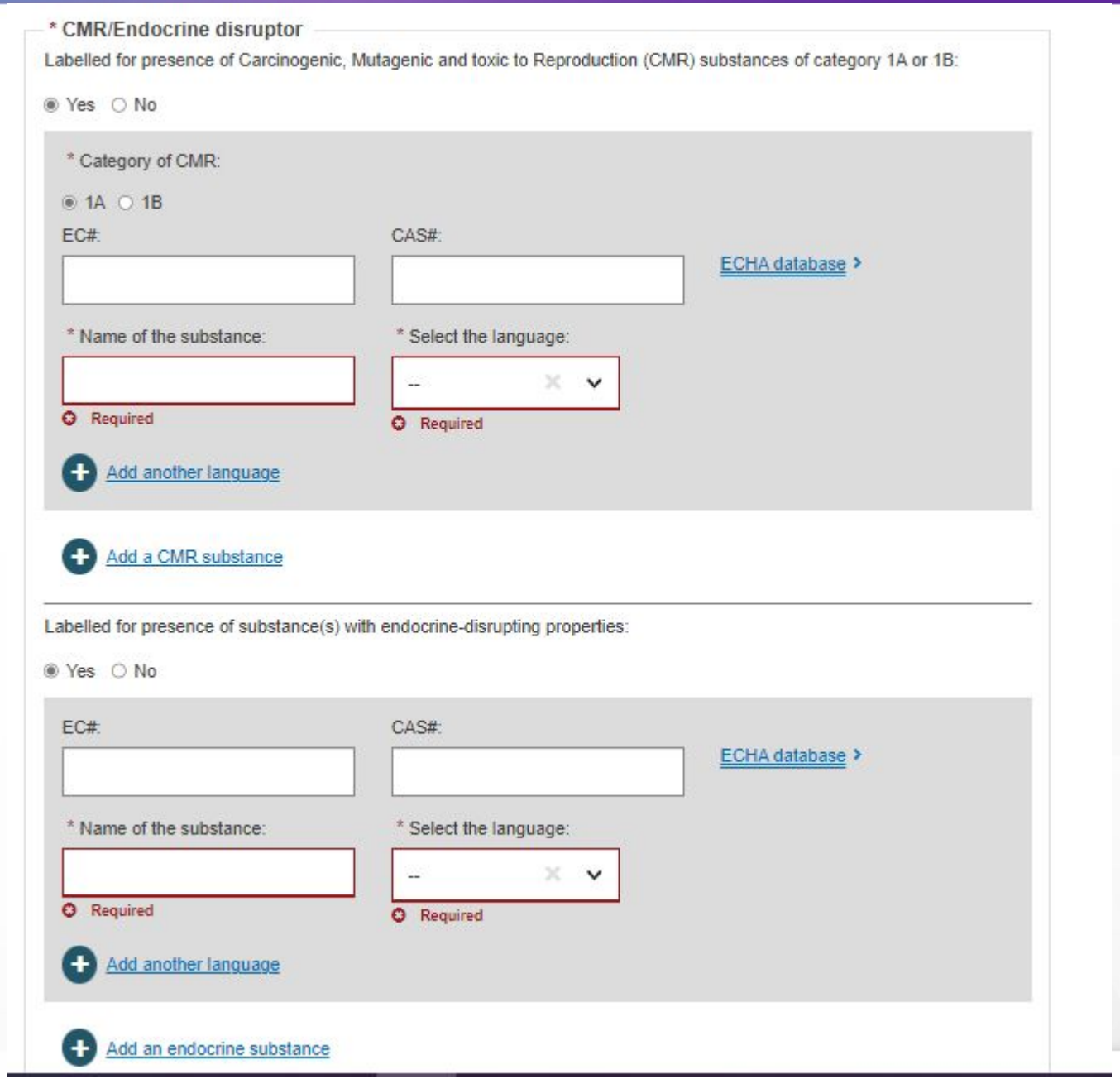
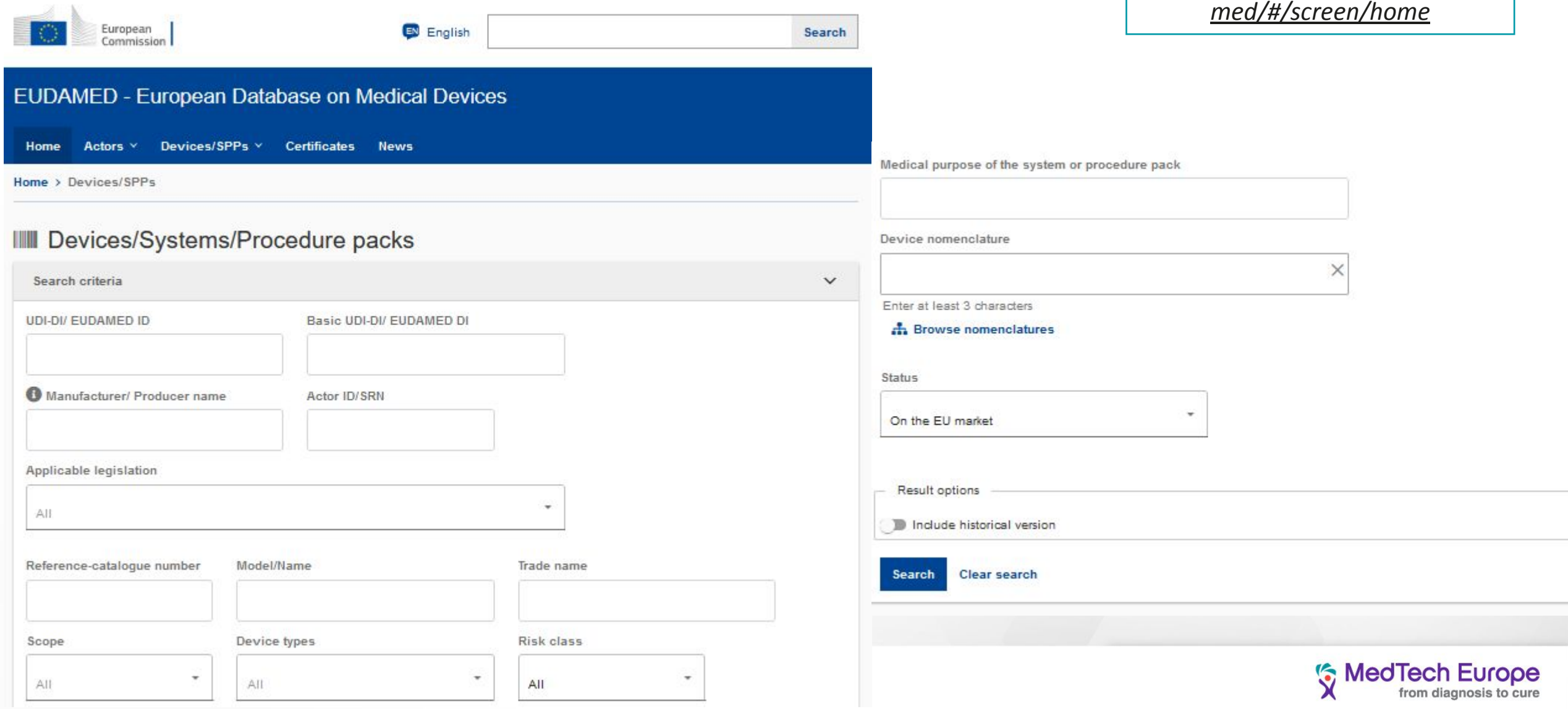
MDR

- Name of the substance (and its translation) is required
- EC# or CAS# only is not sufficient (optional fields)



EUDAMED search function – public site

Available at: https://ec.europa.eu/tools/eudamed/#/screen/home



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