

Health Care Without Harm

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

27 September 2022 Oliver Bisazza

About MedTech Europe

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



OUR



140+
multinational
*medi@@@@@@ationsi*health



50 medical technology associations



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





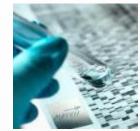






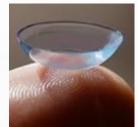




























Medical Devices Regulation in Brief

Former Directives (1990s)

- 1. MDD: Medical Devices

 Directive 93/42/EEC
- 2. <u>AIMDD</u>: 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

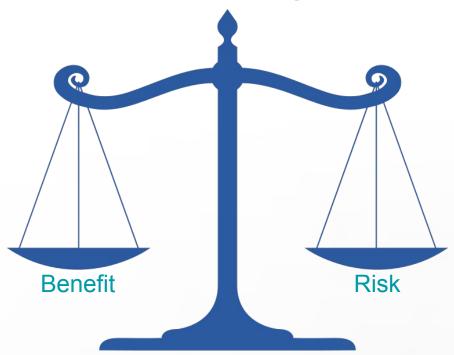
- → Restriction with exemptions to address risk at the waste stage
- → Waste legislation / limited scope (EEE / substances targeted)

- → 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

Medical Devices Regulation



- 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	Independent Audit	Audit results presented to the Medical Devices Coordination	EUDAMED has achieved full functionality following the outcome of the Audit.	End of 6 months transitional period after publication of the notice in the OJEU The use of EUDAMED	End of 24 months transitional period after publication of the notice in the OJEU
modules		Group (MDCG)	Publication of a Commission notice in the Official Journal of the European Union (OJEU) The full EUDAMED system (all 6 modules) is released.	becomes mandatory as regards obligations and requirements related to Actors, Vigilance, Clinical Investigation & Performance Studies and Market Surveillance modules	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.



EUDAMED implementation timeline

2020

2021

Dec

2022

Oct

2023

mid July

mid July

Competent Authorities only

Q3

Q3

?...

European Commission *Playground* Launch Date (may change)

European Commission Production Launch Date (may change)

Fully Mandatory use Mandatory use² **Functional** Actor, VIG, Clinical (Notice in Official Journal) Inv/Perf Studies, **UDID, CERT** Q2 2024 Q2 2026 **Market Surv** ! Shortened timeline! 3 ,Q4 2024 2024 2025 2026 New playground version in every quarter New playground version in every quarter

- 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...)



Actor Registration

UDI & Device Registration

Vigilance & Post Market

Clinical Investigations/

Performance Studies

Market Surveillance

Surveillance

Notified Bodies & Certificates

EUDAMED delay history

	2019			2020			202	2021			2022			2023				2024						
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Initial Plan						26Ma	у			MDR Do 26 May				IVDR Do 26 May										
Delay 1 announced OCT2019																								
Plan 2																								
Delay 2 announced OCT2021																								
Plan 3																_								
Delay 3 announced JUL2022																								

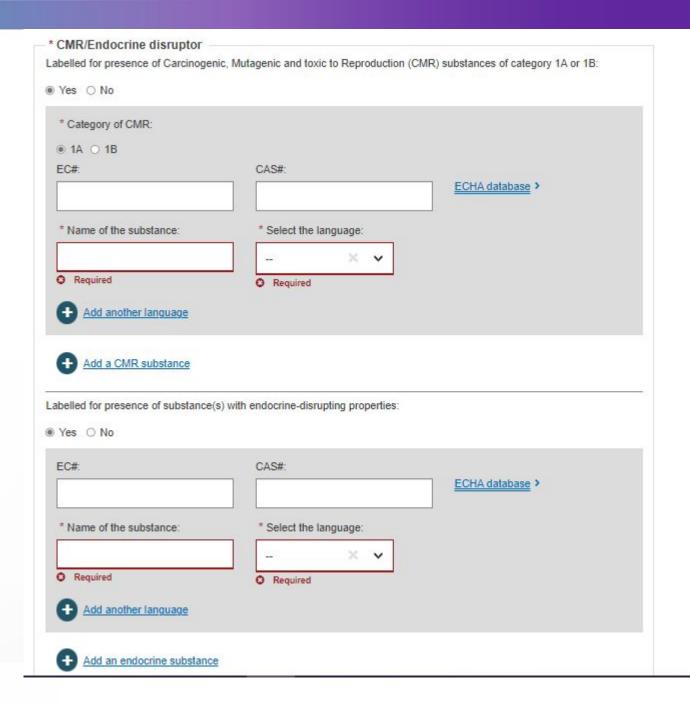
Original date for EUDAMED full functionality by MDR
Delay announced

Planned deployment of fully functional EUDAMED



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/euda
med/#/screen/home

European English Commission	Search	<u></u>
EUDAMED - European Database on Medical Devices		
Home Actors Y Devices/SPPs Y Certificates News		Medical purpose of the system or procedure pack
Home > Devices/SPPs		medical purpose of the system of procedure pack
Devices/Systems/Procedure packs		Device nomenclature
Search criteria	v	×
UDI-DI/ EUDAMED ID Basic UDI-DI/ EUDAMED DI		Enter at least 3 characters Browse nomenclatures
Manufacturer/ Producer name Actor ID/SRN		On the EU market
Applicable legislation	_	
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Reference-catalogue number Model/Name Trade	name	Search Clear search
Scope Device types Risk o	lass	
All T All	•	MedTech Europe from diagnosis to cure

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