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MEETING DOCUMENT

From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices (Medical Devices)
Subject:	Proposal for a Regulation to simplify rules on medical and in vitro diagnostic devices - Commission presentation

Delegations will find in annex the presentation by the Commission services at the meeting of the Working Party on Pharmaceuticals and Medical Devices on 23 March 2026.

MDR/IVDR revision
Commission Proposal

DG SANTE Unit D3, Medical devices



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Agenda

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1. Scope and definitions
2. EUDAMED and UDI
3. International cooperation



Scope and definitions

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Scope

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- include ***accessories for devices without intended medical purpose*** (Annex XVI products) – Art. 1(2) + (4) MDR
- replace “tissues or cells of human origin” by “***substances of human origin***” to reflect new SoHO Regulation 2024/1938 – Art. 1(6)(g)+(10) MDR
- ***MD-IVD combination products*** either subject to MDR or IVDR depending on principal mode of action – Art. 1(7) MDR and Art. 1(4) IVDR

Definitions

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Amendments to existing definitions

- 'medical device' - *"[…] products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) ~~and of those referred to in the first paragraph of this point.~~"* (Art. 2(1), last subparagraph MDR)
- 'generic device group' – "*[…] means a set of devices having the same or similar intended purposes ~~or~~* ***and*** *a commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics"* (Art. 2(7) MDR, Art. 2(8) IVDR)
- deletion of definitions 'nanomaterial, 'particle', 'agglomerate', 'aggregate' (Art. 2(18)-(21) MDR), instead: reference to **COM Recommendation C/2022/3698 on nanomaterial definition** in Annexes I and VIII MDR
- 'clinical data' –addition of '*other studies published in scientific literature* ***on the device concerned***' (Art. 2(48), 2nd indent, MDR)
- 'in vitro diagnostic medical device' – "*[…] to define or monitor~~ing~~ therapeutic measures*" (Art. 2(2), point (f) IVDR)
- 'companion diagnostic' – "*[…] means a device which is essential for the safe and effective use of ~~a~~* ***one or more*** *corresponding medicinal product****(s)*** *to: […]"* (Art. 2(7) IVDR)

Definitions

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New definitions

- ‘well-established technology device’ – Art. 2(72) MDR
- ‘combined study’ – clinical trial combined with performance study and/or clinical investigation (Art. 2(73) MDR, Art. 2(75) IVDR; Art. 2(44) CTR in Biotech Act proposal)
- ‘regulatory sandbox’, sandbox plan’, Union regulatory sandbox’ – main elements of a sandbox (controlled environment for testing a product or regulatory requirements, set up by NCA or EC, limited time, pursuant to sandbox plan – Art. 2(74)-(76), Art. 2(76)-(78) IVDR

Well-established technology device (WET)

Currently – MDCG 2020-6*	Future – proposed Article 2(72) MDR
The common features of the devices which are well-established technologies are that they all have:	'well-established technology device' means a device that belongs to a generic device group, which fulfils the following criteria:
○ relatively simple, common and stable designs with little evolution;	(a) it has simple, common and stable design;
○ their generic device group has well-known safety and has not been associated with safety issues in the past;	(b) it has not been associated with safety issues in the past;
○ well-known clinical performance characteristics and their generic device group are standard of care devices where there is little evolution in indications and the state of the art;	(c) it has well-known clinical performance characteristics and comprises standard of care devices with little evolution in indications and the state of the art;
○ a long history on the market.	(d) it has a long history on the Union market;
Therefore, any devices that meet all these criteria may be considered "well-established technologies".	

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* Extract from MDCG 2020-6: "'well-established technology': this terminology is used in Article 52(5) and Article 61(8) of the MDR, but is not defined in these articles. The term is not restricted to the devices listed in Article 61(6b); Article 61(8) explicitly states that this includes devices *similar to* the exempted devices listed in Article 61(6b), which might be added to that list in future."

Well-established technology device (WET)

Currently

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Article 18(3) MDR	Article 52(4) MDR	Article 61(6)(b) MDR
Implant card	**Sampling of technical documentation**	**Clinical investigations**
Implantable devices, except	Class IIb implantable devices, except	Implantable and class III devices, except
- *sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips or connectors;* - *[cannulas, catheters, feeding tubes, suture pledgets, suture sleeves, suture buttons, gastrostomy buttons, bone tacks, bone wax, bone fillers, bone substitutes, stem centralisers, diaphyseal obturators, radiography markers, fiber ligatures, haemostatic fleeces and sponges, tubal extraluminal ligation devices, transpalatal distractors, nails, anchors, textile braids, orthodontic devices, dental barriers, dental veneers, suspensory fixations and cinches, springs for skull enlargement, pacing wires and leads, and lead caps]* *(Discussion ongoing)*	- *sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips or connectors;* - *cannulas, catheters, feeding tubes, suture pledgets, suture sleeves, suture buttons, gastrostomy buttons, bone wax, bone fillers, bone substitutes, stem centralisers, diaphyseal obturators, radiography markers, fiber ligatures, transpalatal distractors, nails, anchors, spinal posterior fixations, textile braids, dental implants, orthodontic devices, dental barriers, suspensory fixations and cinches* *(COM Delegated Act C(2026)1798 of 20/3/2026)*	- *sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips or connectors;* - *cranial perforators, cranio-blades, catheter passers, patties and strips, magnets for implantable pulse generators, port plugs, stylets and stylet guides, needles, needle holders, forceps, cannulas, atrioseptostomy balloon catheters, catheters coated with anticoagulants, blood bags incorporating anticoagulants, port catheters, introducers, dilators, ventricular drains, feeding tubes, suture pledgets, suture sleeves, suture buttons, gastrostomy buttons, bone tacks, bone wax, bone fillers, bone substitutes, stem centralisers, diaphyseal obturators, radiography markers, fiber ligatures, tubal extraluminal ligation devices, transpalatal distractors, nails, anchors, spinal posterior fixations, textile braids, dental implants, orthodontic devices, dental barriers, dental veneers, suspensory fixations and cinches, reusable surgical instruments, springs for skull enlargement, guidewires, pressure wires, pacing wires and leads, snares, lead caps, fixation and connector tools, endovascular embolisation coils, embolisation particles, cables, shunts and internal defibrillation paddles* *(COM Delegated Act C(2026)1809 of 20/3/2026)*

Well-established technology device (WET)

Future

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Article 18(3) MDR	Article 32 MDR	Article 52(3)+(4) MDR	Article 61(6)(b) MDR	Article 86(2) MDR
Implant card	**Summary of safety and clinical performance (SSCP)**	**Sampling of technical documentation**	**Clinical investigations**	**Evaluation by NB of periodic safety update report (PSUR)**
Implantable devices, except WET	Class III and class IIb implantable devices, except WET	Class III and class IIb implantable devices, except WET	Class III and class IIb implantable devices, except WET	Class III and class IIb implantable devices, except WET

Well-established technology device (WET)

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- Possibility to amend WET definition by delegated act – Art. 3(1) MDR

- Possibility to draw up non-exhaustive lists of WET (or non-WET) by implementing act – Art. 3(2) MDR



EUDAMED and UDI

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EUDAMED (1) – main change

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What: Amendment to Article 33 MDR / 30 IVDR in order to provide for the **possibility** to have one or more electronic systems developed outside EUDAMED

Rationale: flexibility to adapt to future needs. The provision does not impose the development of a module(s) outside EUDAMED, but only provides for the option of doing it, should this be considered relevant and useful (e.g. CI/PS module, which could be developed and directly integrated with the CTIS).

Conditions:

- If module(s) are developed outside EUDAMED, they must still be interoperable with the other EUDAMED modules
- All conditions that apply to the EUDAMED modules would apply to the ones developed outside EUDAMED (e.g. national database compatibility, technical support, data protection etc)

EUDAMED (2) – other changes

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- Person responsible for regulatory compliance data **not public** – personal data
- Data on legal or natural persons other than the manufacturer who design and manufacture the device **not public*** – sensitive data
- **Removal of redundant information** from Art. 29 MDR (assignment of Basic UDI-DI by manufacturer and inclusion of Basic UDI-DI in the certificates) – covered by relevant other articles
- **Inclusion of persons referred to in Article 22(1)** of MDR in the list of Art. 31 as economic operators that must register as Actors in EUDAMED – such economic operators have obligations in EUDAMED which cannot be fulfilled if they are not registered.
- Art. 123(3)(d) MDR / 113(3)(f) IVDR – **national databases should retrieve data from EUDAMED** – avoid duplication and risk of mismatch of data

* **typo** in new Art. 28 (3) MDR which refers to point 13 instead of point 9 of Annex VI Part B

EUDAMED (3) – Annex VI parts A and B MDR/IVDR

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What: Amendment to parts A and B of Annex VI MDR/IVDR in order to streamline reading and have clear distinction between economic operators' data elements and device data elements

In particular:

- Part A now **only contains economic operators data elements** (no change in data elements to be provided) – inclusion of 'digital contact' to ensure digitalisation element
- Part B now **only contains device/SPPs data elements**.
- Some data elements were duplicated in previous version of Part A and B, now they have been merged to avoid overlaps (e.g. Basic UDI-DI, risk class etc).
- Market distribution data element added for Class I devices.

Unique Device Identification (UDI)

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What: Overall streamlining of UDI Articles in MDR and IVDR for **better clarity and readability** – elimination of redundancies, all assignment obligations placed in the same article, registration in EUDAMED obligations kept in separate article

Moreover:

- Introduction of requirements for UDI issuing entities to take into account the **interests of micro and small sized enterprises**
- Amendment to Annex VI (delegated act) can be carried out also based on experience gained in the implementation of the UDI system – lesson learned from Master UDI-DI and in order to be 'future proof', should specific needs for specific devices arise
- Annex VI Part C: amendment of **definition of Basic UDI-DI** – previous definition partially overlapping with UDI-DI definition. New definition aligns with **Guidance MDCG 2018-1**, documents of reference used by manufacturers for Basic UDI-DI assignment

Summary of Safety and (Clinical) Performance (SS(C)P)

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SS(C)P

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Summary of safety and clinical performance (MD)

- Reduction of **scope** (only class IIb implantable and class III devices)
- SSCP should be written in a way that is clear to **intended user** (removal of reference to patients)
- **Removal** of dedicated notified body validation
- **Management** in EUDAMED entirely by manufacturer

Summary of safety and performance (IVD)

- Reduction of **scope** (only class D and class C CDx and self-tests)
- SSCP should be written in a way that is clear to **intended user** (removal of reference to patients)
- **Removal** of dedicated notified body validation
- **Management** in EUDAMED entirely by manufacturer
- Removal of elements **duplicated in IFU** (IFU will be public through EUDAMED)



International cooperation

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Objective of Articles 108a-c

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What?

- Promote **global convergence** and **uphold EU values** 🌍
- Facilitate **regulatory cooperation & efficiency** 🔄

Why?

- Contribute to **high levels of public health and patient safety**
- Support **fostering innovation** 🚀
- Enhance **efficiency of regulatory compliance** ⚙

Facilitate: timely availability of devices for patients in the Union

Reduce: duplication of **activities** of notified bodies, competent authorities and manufacturers, ultimately **reducing costs** for EU manufacturers

Maintain: strategic competitiveness & the EU's role as a **trusted global reference** authority and jurisdiction

Enable: more efficient access to third-country markets for EU industry

Strengthen: the Union's role in **International regulatory cooperation & development of global principles, standards and guidance**

How? Articles 108a, 108b and 108c

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108a

Regulatory cooperation

With the support of Member States, the Commission **shall**:

- Pursue **international regulatory cooperation**
- Contribute to **global principles, standards and guidance**
- Participate in international fora (e.g. IMDRF, MDSAP)

108b

Reliance mechanisms

The EU **may** participate in:

- Bilateral
- Multilateral reliance activities (e.g. MDSAP)

Enables use of:

- Assessments, inspections and regulatory decisions of third countries

Subject to:

- Equivalent level of health and safety protection
- Transparency, oversight and confidentiality safeguards

108c

Capacity building

With the support of Member States, the Commission **may** provide:

- Regulatory capacity in third countries via technical assistance, training, exchange of experts, best practices
- Financed via: Union programmes or external instruments*

** Applicable to all three arms*

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Thank you!

