Congenius

5-minute guide:

MDR 2.0 proposal | Key implications for Clinical Affairs

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The European Commission's proposal COM (2025) 1023 final, aims to simplify and reduce the regulatory burden of the EU Medical Devices Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR).

The MDR draft, widely referred to within the medical device industry as MDR 2.0, was published by the Commission on 16 December 2025 and has been submitted to the European Parliament and the Council under the ordinary legislative procedure for adoption.

In this 5-minute guide, our Head of Clinical Dr. Sarah Bosshard shares an overview of three major proposed changes in MDR 2.0 that will affect clinical activities.

The changes outlined in the following pages are proposed, and subject to modifications.

Reduced clinical document burden

Expanded Well-Established Technology (WET) framework

Enhanced equivalence pathway

Reduced clinical document burden

Summary of Safety and Clinical Performance (SSCP)

The SSCP will become obsolete, except for Class IIb and III non-WET devices. A summary of the changes is provided below:

- “For Class IIb implantable devices and for Class III devices, **other than custom-made or investigational devices and well-established technology (WET) devices**, manufacturers must draw up an SSCP”
- The Clinical Evaluation Report (CER) and where applicable the SSCP should be updated “whenever those data and findings obtained from PMCF provide information relevant for the confirmation of safety and performance of the device”
- To reduce burden and enhance cost-efficiency, the patient-specific part will not be required
- No separate validation of the SSCP by the Notified Body is needed

Reduced clinical document burden

PMCF Evaluation Report (PMCF ER)

The PMCF ER will become obsolete as noted below:

- “The manufacturer shall analyse the findings of the PMCF and document the results in ~~a PMCF evaluation report that shall be part of~~ the **clinical evaluation report** and the technical documentation”

- Updates should be done “**whenever those findings provide information relevant for confirmation of safety and performance**”

Reduced clinical document burden

Periodic Safety Update Report (PSUR)

A reduction in the PSUR cadence is also proposed:

- **Class IIb & III devices |** From annually to every two years, or when there's a significant change in the benefit-risk determination or in the acceptability of undesirable side-effects
- **Class IIa devices |** Updated when necessary (e.g., if significant risks arise)
- **Custom-made devices (CMDs) |** No PSUR required

Expanded WET framework

WET device definition

Similar to MDCG 2020-6, Article 2 point (72) in MDR 2.0 defines Well-Established Technology (WET) devices:

“well-established technology device” means a device that belongs to a generic device group, which fulfils the following criteria:

a) it has simple, common, and stable design

b) it has not been associated with safety issues in the past

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

d) it has a long history on the Union market

Expanded WET framework

WET device scope expansion

On 20 March 2026, the EU Commission adopted two delegated regulations, C (2026) 1809 and C (2026) 1798, amending the MDR (EU) 2017/745 regulation by expanding the list of WET devices.

- The original MDR listed 12 device types as WET - the expanded list now covers approximately 67 device types
- MDR 2.0 (Article 3) clarifies that the expanded WET device list is non-exhaustive
- Devices not explicitly included may still be justified as WET by demonstrating compliance with the Article 2 (72) criteria

The extension list for WET devices highlights the EU Commission’s commitment to addressing the MDR revision with urgency and seriousness.

Expanded WET framework

A simplified approach for WET devices

C (2026) 1809 and C (2026) 1798 provide simplified approaches for manufacturers of some WET devices through:

- The exemption from the requirement to perform clinical investigations, if adequate data exists from recognised alternative sources
- The exemption from the obligation to perform an assessment of the technical documentation for every device during the conformity assessment procedure

The last point is particularly interesting as MDR 2.0 Article 52 (3) states that "**Class III devices can be well-established technology** devices and shall be subject to a conformity assessment as specified in Chapters I and III of Annex IX, including an assessment of the technical documentation of one representative device **per generic device group**."

Enhanced equivalence pathway

Proposed expansion of the Biological & Clinical equivalence criteria

Under MDR 2.0 the biological and clinical indents of Annex XIV, Part A, (3) have been expanded:

- **Biological:** the device uses the same **or similar** materials or substances in contact with the same human tissues or body fluids for a similar kind and duration of contact and similar release characteristics of substances, including degradation products and leachables
- **Clinical:** the device is used for the same **or similar** clinical condition or purpose, including similar severity and stage of disease, at the same site in the body, in a similar population, including as regards age, anatomy and physiology; has the same kind of user; has similar relevant critical performance in view of the expected clinical effect for a specific intended purpose
- The characteristics listed must be similar to the extent that there would be **no clinically significant difference in the safety and clinical performance** of the device

Enhanced equivalence pathway

Waived contract with equivalent device manufacturer

- Considerations of equivalence shall be based on proper **scientific justification**
- Manufacturers must clearly demonstrate that they **have sufficient levels of access** to the data relating to devices with which they are claiming equivalence to justify their claims
- According to Article 61 (5), the **contract with an equivalent device manufacturer is now waived**, i.e., “a manufacturer of a device demonstrated to be equivalent to an already marketed device manufactured by a different company can avoid performing a clinical investigation provided that the original clinical evaluation has been performed in compliance with MDR requirements and the manufacturer provides clear evidence to the notified body”

In summary | What's the overall impact for clinical?

The major proposed clinical changes in MDR 2.0 mean that:

- SSCPs may become obsolete for certain devices
- PMCF ERs will no longer be required
- PSUR cadence may reduce
- More devices will be considered as WET, with a simplified regulatory pathway for these devices
- Equivalence parameters will be broadened and contracts with equivalent device manufacturers are waived

For clinical teams, this means **efficiency gains** via reduced administrative tasks, fewer clinical investigations and technical documentation assessments for WET devices, and ultimately, **reduced regulatory burden** and **accelerated market access**.

Should you have a clinical challenge related to your medical device, contact our experts today.

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