Clinical evidence for well-established devices and legacy devices under EU-MDR

Definitions for "legacy devices"

IMDRF/CYBER WG/N60FINAL:2020
Principles and Practices for Medical Device Cybersecurity

[…] Legacy Medical Device (syn. Legacy Device): medical devices that cannot be reasonably protected against current cybersecurity threats […]

Section 6.6
For purposes of this IMDRF guidance, medical devices that cannot be reasonably protected (via updates, and/or compensating controls) against current cybersecurity threats are considered legacy devices. The legacy condition represents an especially complex challenge for the present state of the healthcare ecosystem globally since device cybersecurity may not have been considered in the initial device design and maintenance for many devices in use today.

MDCG 2020-5: Registration of legacy devices in EUDAMED

[…] devices, which can continue to be placed on the market under Directive certificates by virtue of Article 120(3) of Regulation 745/2017 (MDR), and Article 110(3) of Regulation 746/2017 (IVDR) after the relevant MDRs application dates […]

MDCG 2020-6: Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC

[…] this is considered to include all devices previously CE marked under the European Medical Devices Directive 93/42/EEC (MDD) or Active Implantable Medical Devices Directive 90/385/EEC (AIMDD) […]

Definition for "Well-established Technologies" (WET)

- **Well-Established Technology is mentioned in EU-MDR Art. 52(5) of the EU MDR but is not clearly defined.**

MDCG 2020-6: Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC

[…] The common features of the devices which are well-established technologies are that they all have:

- relatively simple, common and stable designs with little evolution;
- their generic device group has well-known safety and 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;
- a long history on the market.

Therefore, any devices that meet **all** these criteria may be considered "well-established technologies". […]

"legacy devices" ≠ "WET devices" ⟹⟹

Different kind of data must be used in order to prove the continued safety and performance of the devices as well as conformity with GSPRs

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Well-established technologies (WET) vs. legacy devices

- The concept of "legacy" does **NOT** include new versions of a legacy device or a WET device. If a manufacturer intends to process with a design change and/or improvement, they must refer to EU-MDR Art. 120(3) and MDCG 2020-3 to determine whether this change is ''significant'' as per EU-MDR or not.

- If the device is a WET device as per EU-MDR Art. 52.4 & 52.5, a rationale supporting the determination must be included in the clinical evaluation to justify the type of clinical data used.

- **Sufficient clinical evidence for WET devices vs. legacy devices**

MDCG 2020-6: [...] **"sufficient clinical evidence"** is understood as "the present result of the qualified assessment which has reached the conclusion that the device is safe and achieves the intended benefits". It is important to note that clinical evaluation is a process where this qualified assessment has to be done on a continuous basis. [...]

MDCG 2020-6 – Appendix II
Suggested hierarchy of clinical evidence for confirmation of conformity with relevant GSPRs under the MDR

1. Results of high quality clinical investigations covering all device variants, indications, patient populations, duration of treatment effect, etc.
2. Results of high quality clinical investigations with some gaps
3. Outcomes from high quality clinical data collection systems such as registries
4. Outcomes from studies with potential methodological flaws but where data can still be quantified and acceptability justified, e.g. literature sources
5. Equivalence data (reliable / quantifiable) BUT equivalence must be established as per EU-MDR criteria
6. Evaluation of state of the art, including evaluation of clinical data from similar devices as defined in Section 1.2 of MDCG 2020-06 ***Note:*** *This is not considered clinical data under EU-MDR, but it can be considered supportive of confirmation of conformity to the relevant GSPRs for WET devices* **ONLY**
7. Complaints and vigilance data; curated data ***Note:*** *not generally considered a high quality source of data due to limitations in reporting. It may be useful for identifying safety trends or performance issues.*
8. Proactive PMS data, such as that derived from surveys
9. Individual case reports on the subject device
10. Compliance to non-clinical elements of common specifications considered relevant to device safety and performance
11. Simulated use / animal / cadaveric testing involving healthcare professionals or other end users ***Note:*** *particularly in terms of usability, such as for accessories or instruments.*
12. Pre-clinical and bench testing / compliance to standards

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Clinical requirements for Well-established technologies (WET)

- Although the Directives indicate that data shall be collected in the post-market phase for all devices, in practise this may not be possible for WET devices not associated with safety concerns and/or with no innovation as they are less likely to be the subject of research. For this reason, in some cases, it may be necessary for the manufacturer to undertake PMCF activities to generate new clinical data prior to EU-MDR certification in order to enable an evaluation of the safety and clinical performance of a WET device in relation to an evolving state of the art.

- Acc. to EU-MDR, Annex XIV, **ONLY** for low-risk, standard-of-care, WET devices that belong to a wider generic group, it may be sufficient to use clinical evidence of lower level to confirm conformity with relevant GSPRs. This may be supported by PMS clinical data provided that
  - ✓ a QMS system is in place to allow the systematic collection and analysis of any complaints and incident reports
  - ✓ the collected data support the safety and performance of the device.

- Acc. to EU-MDR Art. 61.6, the requirement to perform clinical investigations **shall** not apply to implantable and class III devices belonging to a specific subset of WET, i.e. sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, etc., for which the clinical evaluation is based on sufficient clinical data and is in compliance with the CS, if available.

Note: The basic clinical evaluation requirements for legacy devices described in Art. 61(6a) and the WET devices of Art. 61(6b) are the **same**: "sufficient clinical data" and compliance to CS. The difference is that WET devices are not explicitly required to have had prior certification under the Directives to be exempted from the requirement for clinical investigations that otherwise apply to class III and implantable devices.

- The clinical evaluation of WET devices can be based on data pertaining to similar devices BUT these data may only be used as indirect supportive data and not as pivotal.

- The clinical evaluation of WET devices can be mainly supported by PMS data based on the hierarchy of clinical evidence for legacy devices (see previous page).

- **Acc. to MDCG 2020-6 – Appendix II,** well-established technologies may be able to confirm conformity with the relevant GSPRs via an evaluation of cumulative evidence from additional sources as listed below. Reliance solely on complaints and vigilance is **not** sufficient.

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Clinical requirements for Legacy Devices

- Legacy devices are **not** exempted from EU-MDR PMS and PMCF requirements, which become mandatory from 26 May 2021 (DoA date).
- There is **no grandfathering provisions for the transition to EU-MDR**. **All** legacy devices need to be "re-certified" under EU-MDR using one of the conformity assessment procedures specified in the Regulation (refer to Art.5 & 52).
- The clinical data previously used for conformity assessment in the Directives may not provide sufficient clinical evidence for EU-MDR requirements. As a consequence, the clinical evaluation of legacy devices must be revised in order to comply with EU-MDR Art. 61 &n Annex XIV(1a).
- The required level of evidence for legacy devices **shall** be identified by the manufacturer as part of the clinical evaluation **planning**.
- Legacy devices are presumed to have been supported by clinical data. Therefore, the **FIRST** EU-MDR conformity assessment of a legacy device can be based on the pre- and post-market clinical data generated under the Directives. However, these data may not be adequately comprehensive to provide sufficient clinical evidence under EU-MDR. For this reason, a gap analysis is required to determine if and what kind of additional data are required.
- Based on the gap analysis results, it is often necessary to initiate PMCF activities as PMCF activities under the Directives were not usually based on collection of real-world data or post-market clinical investigations. For this reason, it **shall** be verified that PMCF studies have been properly conducted under the Directives **unless** a proper justification exists.
- MDCG 2020-6 specifies that controlled clinical investigations are generally the preferred method for collecting clinical data as part of PMCF studies for legacy devices. Another option to gather relevant clinical data is the **combinatorial** analysis of systematic reviews of literature data with the evaluation of results from PMS activities, such as clinically relevant surveys or registries.
- When the clinical evaluation of a legacy device under the Directives, was based on equivalence, equivalence will have to be reconfirmed and demonstrated under the augmented EU-MDR requirements (clinical, technical and biological characteristics).
- **Acc. to MDCG 2020-6 – Appendix II,** class III legacy devices and implantable legacy devices which are not well-established technologies should have sufficient clinical data as a minimum at level 4. Reliance solely on complaints and vigilance is not sufficient