WHITEPAPER

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EU MDR Transition Period Extension

www.makrocare.com

medtech@makrocare.com

On May 26, 2021, the Medical Device Regulation (MDR 2017/745) became effective. The transitional period for CE certifications issued under the Medical Device Directive (MDD 93/42/EEC) and Active Implantable Medical Device Directive (AIMDD 90/385/EEC) was about to end by May 26, 2024. Despite the steady increase in the number of notified bodies designated in accordance with Regulation (EU) 2017/745, the overall capacity of notified bodies is still not sufficient to ensure the conformity assessment of the large number of devices covered by certificates issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC before 26 May 2024.

It appears that a large number of manufacturers, especially small and medium-sized enterprises, are not sufficiently prepared to demonstrate compliance with the requirements of Regulation (EU) 2017/745, in particular when the complexity of those new requirements is taken into account. Therefore, it is very likely that many devices that can lawfully be placed on the market in accordance with the transitional provisions provided for in Regulation (EU) 2017/745 will not be certified in accordance with that Regulation before the end of the transitional period, which leads to the risk of shortages of medical devices in the Union.

To offer medical device manufacturers additional time to certify their products in accordance with the EU Medical Devices Regulation, an amendment to lengthen the transition period for medical devices was proposed before the European Commission in January 2023. This was done in response to concerns that the Regulation might cause a shortage of life-saving products. The plan would also eliminate the MDR's and the *In vitro* Diagnostic Medical Devices Regulation's "sell-off" date requirement.

The European Commission agreed with the proposed amendment, Regulation (EU) number 2023/607 was quickly adopted by the European Parliament and Council and then published in the Official Journal of the European Union on March 20, 2023. The new Regulation extends the transitional periods outlined in Regulations (EU) Nos. 2017/745 (MDR) and 2017/746 (IVDR).

According to the, Regulation (EU) number 2023/607, the date for the transition period is moved from May 26, 2024, to December 31, 2027, or December 31, 2028, depending on the device's risk class. Low and medium-risk devices would have until the end of 2028 to complete a conformity assessment, whereas high-risk devices would be subject to the shorter transition period ending in 2027.

Transition timelines	Devices
26 May 2026	Class III custom-made implantable devices
31 December 2027	Devices that are Class III or Class IIb implantable devices under the MDR and that are covered by current MDD/AIMDD Certifications (as of 2023/03/20) but do not include well-established technology (WET)
31 December 2028	Class IIb devices (excluding Class IIb implantable non-WET), Class IIa devices, Class I sterile devices, or Class I devices having a measuring function that are covered by valid MDD/AIMDD Certificates as of 2023/03/20; Devices for which the declaration of conformity was created prior to May 26, 2021, but which do not need Notified Body certification under the MDD now need Notified Body certification under the MDR

The following conditions must all be met in order for the prolonged transition period to take effect:

- Have a valid MDD/AIMDD certificate as of May 26, 2021.
- Never been withdrawn by a Notified Body.
- Submitted a formal application to a Notified Body for conformity assessment no later than May 26, 2024, for which a written agreement must be executed by the manufacturer and Notified Body no later than September 26, 2024.
- Had no significant changes in the device's design or its intended purpose, and in case the device does not present unacceptable health or safety risks.

In addition, the manufacturer must implement a quality management system by May 26, 2024.

In certain conditions, MDD/AIMDD certifications that were still in effect on May 26, 2021, but that had expired prior to March 20, 2023, will now be regarded as being in effect until the extended transition dates.

Devices that, as of May 26, 2021, did not require a Notified Body to be involved in the conformity assessment procedure may be marketed or put into service until December 31, 2028, even if the MDR now requires one.

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