Statement Confirmation Letter

in the framework of Regulation (EU) 2023/607

The MDR was amended by Regulation (EU) 2023/607, which came into force on 20 March 2023, resulting in the extension of the transition period and the removal of sell-off dates.

Regulation (EU) 2023/607 provides for the renewal of certain certificates of the Medical Device Directive (MDD).

However, the expiry dates stated on these certificates will not change, making it difficult to determine whether a product may still be legally placed on the market or not.

The new "Notified Body Confirmation Letter" form is to be used by Notified Bodies to confirm that the manufacturer including the affected devices, fulfils the requirements laid down in Regulation (EU) 2023/607 and is therefore eligible for the extended transitional period.

This form helps the competent authorities, healthcare professionals, users, authorized representatives and other markets that recognize the CE marking to determine whether the devices can still be lawfully placed on the market in accordance with the MDD certificate.

<u>Essential renewal conditions:</u>

- **Permanent compliance with MDD**
- **No significant changes in design and intended purpose**
- **No unacceptable risk to health or safety**
- **Manufacturer's quality management system (QMS) in place by 26 May 26, 2024 pursuant to MDR requirements**
- **Application for conformity assessment submitted by May 26, 2024, and a contract between manufacturer and Notified Body in place by September 26, 2024**

The transition timelines that apply to the devices covered by the Notified Body Confirmation Letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

26 May 2026:	**for Class III custom-made implantable devices**
31 December 2027:	**for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)**

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31 December 2028:	**for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function**
31 December 2028:	**for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)**

The Confirmation Letter issued by the Notified Body is expected by the end of May 2024 at the latest.

Sincerely,

Stefanie Bochtler
Teamlead Regulatory Affairs