just a heartbeat away
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Statement

According to the Regulation (EU) 2023/607 amendment to article 120(2) of MDR:

Extends the validity of certificates issued under the Medical Devices Directives (MDD) that were valid on the day of the MDR's date of application (26 May 2021) and have not been withdrawn by a Notified Body. The extension is directly applicable, so that Notified Bodies are not required to change the date on the individual certificates. The length of the extension of the certificate's validity corresponds to the length of the extended transition period laid down in the proposed Article 120(3a) to (3c) of the MDR.

The extension is conditional on the manufacturer signing a contract with a Notified Body for the conformity assessment of the device in question at the moment of expiry.

- If this has not occurred, prior to the expiry of the CE certificate, a national competent authority may: (i) grant a derogation from the applicable conformity assessment procedure in accordance with Article 59 of the MDR; or (ii) require the manufacturer to carry out the conformity assessment procedure within a specific time period under Article 97 of the MDR.

This extends the transitional period for devices covered by CE certificates or declarations of conformity issued under the Directives (i.e., "legacy devices") from 26 May 2024 to:

- 31 December 2027 for class III devices and class IIb implantable devices (except for sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors).
- 31 December 2028 for other class IIb devices, class IIa devices and for class Is and Im devices.

Manufacturers will need to fulfill certain conditions to rely on the extension under Article 120(3):

- The devices **continue to comply** with the Directives.
- The devices do **not undergo significant changes** in design and intended purpose.
- The devices do **not present an unacceptable risk** to health or safety. The concept of "unacceptable risk to health and safety" is set out in Article 94 and 95 of the MDR. No systematic check of the device's safety is required.

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- No later than by 26 May 2024, the manufacturer has **put in place a Quality Management System** (QMS) in compliance with Article 10(9) of the MDR. No specific attestation, i.e. no a self-declaration or a verification of the appropriateness of the QMS by a Notified Body, is required. The submission of an application for conformity assessment to a Notified Body will be interpreted as an implicit confirmation that a QMS is in place and compliant with MDR.

- No later than by 26 May 2024, the manufacturer has **lodged a formal application for an MDR conformity assessment** for the legacy device, and by 26 September 2024 the parties have signed a written agreement for such conformity assessment.

Rossmax Swiss GmbH (certificate no. TW19/20056) fulfills the amendment to article 120(2) of MDR and in progress to sign MDR contract with SGS Belgium (Notified Body 1639); accordingly to the amendment to article 120(3), extends the transition period to Dec 31, 2028 of Class IIa products, we'll provided sequentially the self – declaration of extension and SGS confirmation letter once the contract signed.

Yolanda Lin

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Yolanda Lin, Management representative