Enforcement mechanism of the European parliament resolution(decision) REGULATION (EU) 2023/607 of March 2030 on the transitional grace periods granted for the implementation of rules and procedures of MDR and IVDR

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First: Medical devices and equipment

Regarding applying for registration and obtaining import approvals,

local manufacturers and importing companies to which the European Parliament's decision of March 2023 applies regarding extending the grace period under the quality certificates issued between May 25, 2017 - May 26, 2021 and valid on May 26, 2021, in accordance with the following European regulations **and haven't been withdrawn**:

- **Medical Device Directive 93/42/EEC**
- **Active Implantable Medical Devices Directive 90/385/EEC**

- Shall submit the following documents, indicating that the grace period applies to the relevant medical devices and in vitro diagnostics and mentioning the deadline of this period:

1. A letter issued by the legal manufacturer.
2. A letter issued by the Notified body.

In case of quality certificates that were valid on May 26,2021 and became expired before March 20,2023 , a letter from the notified body may be submitted stating that the grace period applies for the product provided that its issuance date is before the expiry of the quality certificate .

or:

a letter from the Competent Authority from the country of origin of the medical devices stating the following :

A derogation from the applicable conformity assessment procedure in accordance with Article 59(1) of this Regulation or has required the manufacturer, in accordance with Article 97(1) of this Regulation, to carry out the applicable conformity assessment procedure.

That's in addition to the required documents for the requested service "registration, re-registration, variation, import approval")

Secondly: In vitro diagnostics

Regarding applying for registration and obtaining import approvals for i**n vitro diagnostics** that must require a quality certificate from a **Notified body** according to **IVDR**; local manufacturers and importing companies to which the European Parliament's decision of March 2023 applies regarding extending the grace period under the quality certificates issued before 26th of Mays 2022 according to the following European regulations **and haven't been withdrawn**:

- **In Vitro Diagnostic Medical Device Directive 98/79 EC**

  -Legal manufacturer must submit a letter stating that no major changes occurred in the design and the intended use of the product.

That's in addition to required documents for the requested service "registration, re-registration, variation, import approval"

- To access the European Parliament's decision, please click the following link:
  https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32023R0607

- For further clarification of the European Parliament's decision, you can check the Factsheet issued by the European Union through scanning the following Qr code.

versions

version	Issue date	Amendments
First	29/05/2023	
Second	10/10/2023	Updating the mechanism of implementation to convey (for) more clarification of the European parliament's decision