Notified Body
2764

31.10.2023

Dear Certificate Holder,

As you may be aware, the 93/42/EEC Medical Device Directive was repealed on May 26, 2021, and replaced by the 2017/745 Medical Device Regulation. According to the latest decision, the validity of certifications under the MDD scope has been extended as follows, depending on the risk class of the products:

- For Class III implantable custom-made devices, until May 26, 2026
- For Class III and implantable Class IIb devices, until December 31, 2027
- For non-implantable Class IIb and lower-risk devices, until December 31, 2028
- For Class I devices (reusable surgical instruments) with a higher class under the MDR, until December 31, 2028

During this period, various scenarios may arise for the continuation of surveillance audits for MDD Certifications.

First Scenario:
The certificate holder company must have applied for MDR certification from the Notified Body (NOTICE) that performed the MDD certification and must have signed an MDR certification contract by September 26, 2024. Under these conditions, MDD surveillance audits will continue with the same Notified Body (NOTICE) as specified in the dates above until the MDR certification is completed. If the contract is canceled during the process, the MDD certificate will lose its validity. If you decide to sign a new contract with a different MDR Notified Body during the process, make sure there is no gap between the NOTICE and the new MDR Notified Body contracts, even for a single day.

Second Scenario:
If the certificate holder company has contracted with a different Notified Body for MDR certification, they can make a choice regarding the surveillance audits for MDD certification. The options in this scenario are as follows:

1. If the certificate holder company selects an MDR Notified Body for the surveillance audits of the MDD certification, if possible, the audit rights for the MDD certification can be transferred to the new MDR Notified Body through a tripartite agreement between the former Notified Body, the new MDR Notified Body, and the Certificate Holder Company. To maintain the validity of the certificate, you must have applied to the MDR Notified Body by May 26, 2024, and signed a new MDR certification contract by September 26, 2024. If the application and contract are completed before these dates, the transfer can take place. Once the transfer is completed, the responsibility for the MDD certificate will shift to the new MDR Notified Body, and surveillance obligations will be fulfilled by the new MDR Notified Body.

2. If the certificate holder company wishes to continue surveillance audits of the MDD certification with the former Notified Body, these audits can only be carried out by the former Notified Body (NOTICE) **until September 26, 2024**. After this date, the surveillance audits for the relevant certification will be **automatically transferred to the responsibility of the new MDR Notified Body**. Until September 26, 2024, a tripartite agreement will be established between the firm and the Notified Bodies to facilitate the transfer process.

   This information is clearly stated in Question & Answer (Ref.*) Document 15 published by the European Commission.

Therefore, if you plan to contract with a different MDR Notified Body or have already done so, the surveillance audits of your existing certifications can only be carried out by our organization with a short-term contract **until September 26, 2024**. After this date, as mentioned earlier, the MDR Notified Body where your MDR application is lodged will assume this responsibility.

If you have applied to a different MDR Notified Body, Confirmation of Application and, if signed, Confirmation of Contract must be provided to us by April 26, 2024, at the latest. If only the application has been made, the contract confirmation must be completed and provided to us by September 26, 2024, at the latest.

We trust that this information is helpful, and we wish you success in your endeavors.

Sincerely,

Ref.*: Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices REV. 1

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