Terms and Conditions for Surveillance of Legacy Devices according to MDR Article 120

1. Introduction

This document supplements the General Terms and Conditions for Medical Devices Certification under Regulation (EU) 2017/745 (hereinafter MDR General Terms), specifying the particular provisions for the Surveillance of Legacy Devices according to MDR Article 120.

All the provisions and requirements of the MDR General Terms apply except where differentiation is clearly indicated in this document.

2. Definitions

Legacy devices can be:

- devices which are class I devices under Directive 93/42/EEC (herein after MDD), for which an EC declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure under the MDR requires the involvement of a Notified Body.
- devices covered by a valid EC certificate issued in accordance with the MDD prior to 26 May 2021.

3. Certification process

For the surveillance of legacy devices according to MDR Article 120, the following provisions shall apply, notwithstanding the relevant provisions of the MDR General Terms.

3.1 Starting the certification process

To be read in conjunction with MDR General Terms section 3.3.

- The surveillance of legacy devices according to MDR Article 120 requires that a separate application for this has been submitted and accepted by HTCert.
- A surveillance contract for legacy devices is concluded if the corresponding application is submitted in full and all other requirements set out in Article 120 of the MDR are met.
- It is not mandatory to submit with the application the complete technical documentation in line with HTCert Technical Documentation Submission Guidance for all devices included in the requested scope. Instead, the following apply:
  - the manufacturer provides a self-declaration confirming that the conditions for the extension are fulfilled, stating the end date of the transition period. This declaration shall clearly identify the devices covered by the extension and the certificates concerned.
  - the manufacturer declares that all technical documentations are at a preparation stage and provides a timeline for the submission of the individual technical documentation.
  - HTCert and the manufacturer agree on a plan for the submission of the relevant technical documentation in due time.
  - The following deadlines are set for the submission of the legacy devices' technical documentation:
    - 31 December 2025 for devices in class III and IIb implantable
    - 31 December 2026 for devices in class IIb non- implantable, IIa and Is/Im/Ir.
- Upon signing the contract, HTCert issues a confirmation letter, stating the receipt of the application and the conclusion of the agreement. This confirmation will clearly identify the devices covered by the extension and the certificates concerned.
- If the manufacturer was previously certified by another Notified Body, an additional agreement between HTCert, the manufacturer and the Notified Body that issued the MDD certificates ('tripartite agreement') has to be signed in order to set the arrangements for the transfer of the surveillance in respect to devices covered by the contract.
  If this is not practicable (e.g. termination of business of the outgoing Notified Body), an agreement between HTCert and the manufacturer will be signed to specify the arrangements concerning the appropriate surveillance to be performed.

3.2 Maintaining certification

To be read in conjunction with MDR General Terms section 3.6.

- For the surveillance of legacy devices, the manufacturer shall comply with the obligations arising from all the agreements signed.
- Notifications of changes shall be made in accordance with the MDR General Terms. Legacy devices may not undergo any significant change in the design or intended purpose.