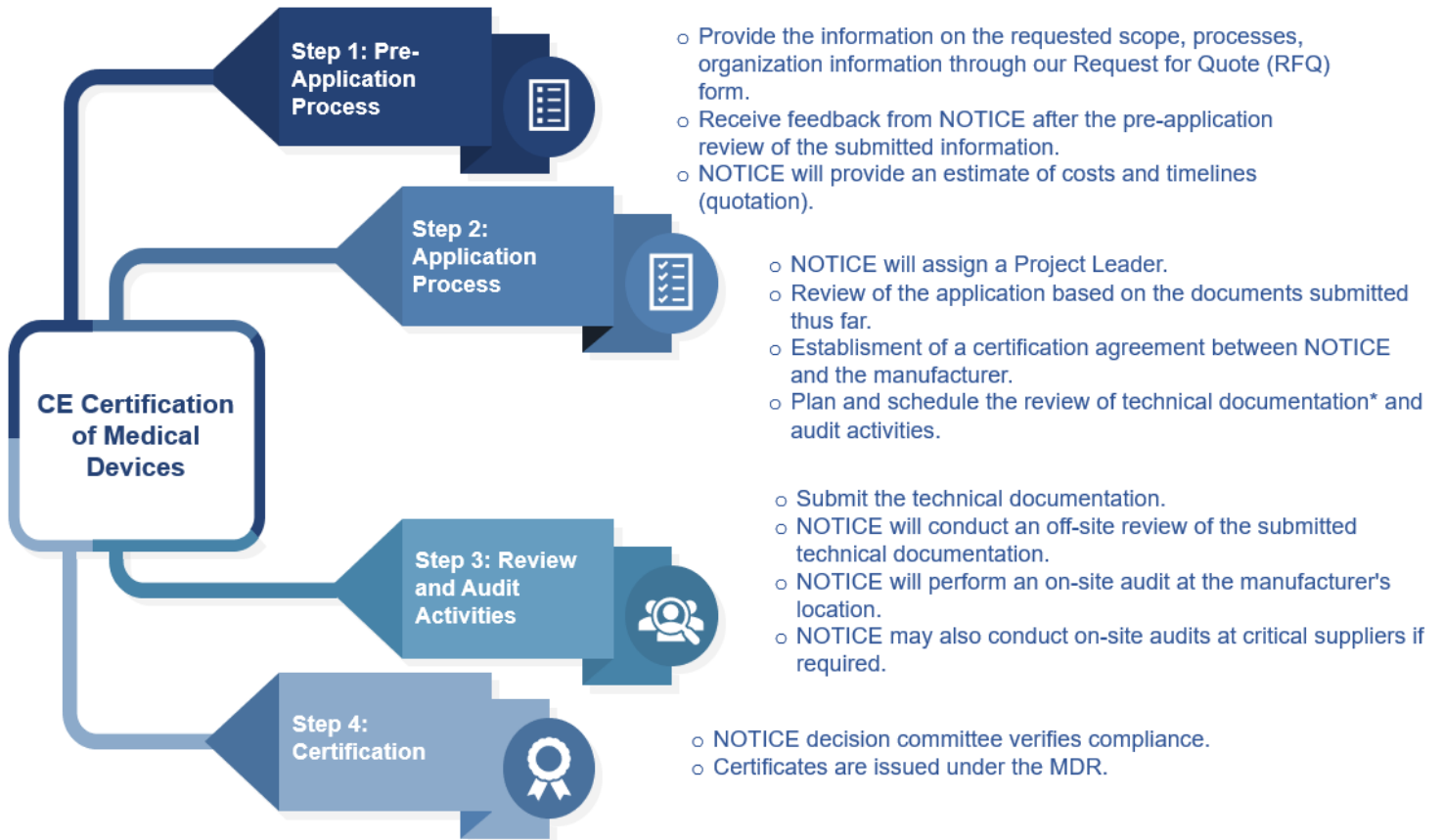


Summary of the Steps Towards CE Certification of Medical Devices Under MDR 2017/745

This leaflet guides you through the certification process: from the initial (pre-) application at NOTICE to the issuance of the certificate.



*NOTICE accepts QMS documents and correspondence in English only.

1. Structured Dialogue

The purpose of a structured dialogue prior to submitting a formal MDR application with NOTICE (pre-application) is to clarify the timing, procedural, and regulatory aspects of the application process, including the required forms & submission documents and any other related aspects. The structured dialogue can also be conducted during the conformity assessment process (i.e. post-application).

2. Request for Quote

The applicant organization provides Notice with information on the requested scope, processes, organization information... through SI.FR.07 Request for Quote (RFQ) Form available on our website. This form gives us the necessary information about the company and devices in order to provide an accurate proposal. The RFQ shall include the requested information and be signed by the manufacturer or their authorized representative.

3. RFQ Evaluation

NOTICE evaluate the received RFQ and decide on their accepting or rejecting based on the internal criteria. In case of acceptance, NOTICE will generate a proposal based on the information you include in the RFQ. Once accepted, the signed proposal will form the basis of the contractual agreement between the applicant organization and NOTICE. On receipt of the signed proposal, NOTICE will assign a dedicated team to the company, including a Project Leader to oversee certification activities. This person will remain the point of contact for all of the company's current and any future certification needs.

4. Application Evaluation

The Project Leader will review your application and the resulting contract for completeness, requesting any additional information required to ensure that NOTICE assigns appropriately qualified Assessors to complete your initial certification.

5. Technical Documentation Assessment

The product reviewers and clinical specialists with the relevant product expertise will be assigned to conduct the technical documentation assessment. The assessment team will review the completeness and content of the documentation, including any additional documents or test results that provide evidence of conformity to the Regulation. They will ask rounds of questions where any gaps are identified. Your product(s) may be subject to additional assessment by specialist reviewers or consultation with a Competent Authority or the EU Commission.

6. QMS Assessment

Once the non-conformities detected in technical documentation assessment are closed, a site audit of the quality management system is conducted.

7. Follow-Up Audits

Follow-up audits are conducted in case the conformity assessment team decides the necessity of verification of closure of the detected non-conformities on site.

8. Auditing Outsourced Processes and Critical Suppliers

Suppliers whose auditing has been deemed necessary by NOTICE, will be audited as a part of the certification process.

9. Final Review

Once the QMS and technical documentation assessments have confirmed compliance to the applicable requirements, a final review of the undertaken activities is performed and, if decided that the requirements are met, certification will be recommended. The decision is submitted to the decision committee.

10. Certification Decision

All NOTICE certification is subject to a final internal approval process. These decisions are taken by NOTICE staff with the appropriate technical and compliance competence. Decision on granting or rejecting the certification is communicated to the client.

11. Certificate Issue

Once approved, the certificates will be issued and provided to the organization both electronically and in hardcopy to the organization. The Client's certificate will be issued in 1 English copy. The issued certificates can be tracked on our website.

12. Short Notice Audits

In case of complaints with objective evidence, NOTICE will perform extraordinary short-notice audits.

13. Unannounced Audits

After the conformity assessment is completed, unannounced site audits are carried out on the facilities of the client at least once within the certification.

14. Subcontractor Audits

The need for subcontractor audits and the time allocated for them may vary depending on the activities outsourced by the manufacturer. Whether an additional audit at a subcontractor's premises is required depends on the level and scope of control the manufacturer maintains over the subcontractor's activities. For this reason, it is crucial that NOTICE is informed about all involved critical subcontractors and suppliers.

15. Surveillance Audits

Surveillance audits are carried out annually to control the client's conformity continuity to MDR 2017/745 requirements. Surveillance audits shall be conducted at least once every 12 months from the certificate date.

16. Change Audits

After signing the agreement, all the planned changes in the client's quality management system or the products shall be communicated to NOTICE via SI.FR.08.11 Planned Change Notification Form which is available at our website. After the evaluation, in case site audit is deemed necessary, the change audit will be performed. This includes changes to:

- The approved quality management system(s) or the covered product range
- The approved device design
- The intended use and claims made for the device
- The approved device type
- Any substances used in or incorporated into the manufacturing of the device
- Changes that could affect compliance with the General Safety and Performance Requirements (GSPR), Common Specifications (CS), or other previously approved solutions
- Legal, commercial, organizational status, or ownership
- Organization and management (e.g., key managerial, decision-making, or technical staff)
- Contact addresses and sites
- Scope of operations under the certified management system
- Major changes to the management system and processes.

17. Re-Certification Audits

At the end of the certification cycle, the NOTICE Project Leader will develop a plan to initiate a new certification period. The renewal audit is usually scheduled at least six months before the certificate's expiration date. During this process, the entire quality management system will be reviewed and audited to ensure its continued effectiveness, considering both internal and external changes, and its relevance to the certification scope.

Certificate renewal audits are conducted prior to the expiration of their validity period as shown below:

Class	Type of Certificate	Validity
Class III	EU QMS Certificate+ EU TD Assessment Certificate	4 Years
	OR EU Quality Assurance Certificate + EU type-examination certificates (MDR 2017/745 Section 4 of Annex X) issued by another Notified Body	Max 4 years, or as long as the validity period of Annex X certificate, whichever is shorter
Class IIb (Implantable, except for WET)	EU QMS Certificate+ EU TD Assessment Certificate	4 Years
	OR EU Quality Assurance Certificate + EU type-examination certificates (MDR 2017/745 Section 4 of Annex X) issued by another Notified Body	Max 4 years, or as long as the validity period of Annex X certificate, whichever is shorter
Class IIb (Non implantable, & Implantable WET)	EU QMS Certificate	5 Years
	OR EU Quality Assurance Certificate + EU type-examination certificates (MDR 2017/745 Section 4 of Annex X) issued by another Notified Body	Max 4 years, or as long as the validity period of Annex X certificate, whichever is shorter
Class IIa	EU QMS Certificate OR EU Quality Assurance Certificate	5 Years
Class I (s/m/r)	EU QMS Certificate OR EU Quality Assurance Certificate	5 Years
Importers/Distributors (article 16(b))	Quality Management Certificate	5 Years

Contact Information

NOTICE d.o.o.

Room 207, 208, World Trade Centre, Dunajska cesta 156, 1000
Ljubljana – Slovenia

Email: info@notice.si

Website: www.notice.si

