EN ISO 13485 CERTIFICATION PROCESS

1. REQUEST FOR QUOTE

The applicant organization provides us with information on the requested scope, proceesses, organizaiton information... through our Request for Quote form.

2. RFQ EVALUATION AND PLANNING AUDITS

We evaluate the received RFQ and decide on their accepting or rejecting based on our internal criteria. In case of acceptance, Certification proposal is is sent to the applicant and upon approval, the audits will be planned.

3. STAGE 1 SITE AUDIT

The following items are checked in stage 1 audits:

- Verification of the scope of the certification and the not-applicable clauses,
- Verification of the adequacy of site conditions to manufacture products/provide services in the certification scope
- Evaluation of the compliance of procedures and operational documents of the Client with ISO 13485 standard and other related requirements
- The client's location, the specific conditions of the site and the personnel's preparedness for stage 2 audit
- Client's awareness and understanding of standard requirements, management system objectives, processes, key performance, and identification of important parties
- Checking whether internal audits and management reviews are planned and whether the management system is ready for stage 2 audit.
- Determining the sites to be visited in stage 2 audit and the respective timeframes
- Evaluating The need to any additional supplier/subcontractor audit,
- Determination of the need for additional assessment personnel during the stage 2 audit,
- Determination of the need for a translator during the stage 2 audit.

4. STAGE 2 SITE AUDIT

Stage 2 is carried out in case no nonconformity is identified in Stage 1 or the identified nonconformities are rectified. The aim is to check the conformity of the client with the applicable regulation, standard and to check the suitability of the documentation prepared by the client.

5. FOLLOW-UP AUDITS

Follow-up audits are conducted in case the audit team decides the necessity of verification of closure of the detected nonconformities on site.

6. 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.

7. CERTIFICATION DECSION

Upon closure all the detected nonconformities, decision on granting or rejecting the certification is taken and communicated to the client.

8. CERTIFICATE ISSUE

The Client's certificate will be issued in 1 English copy. The issued certificates can be tracked on our website.

9. SURVEILLANCE AUDITS

Surveillance audits are carried out to control the client's conformity continuity to EN ISO 13485 requirements. Surveillance audits shall be conducted every 12 months from the certificate date.

10. SHORT NOTICE AUDITS

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

11. 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.

12. RE-CERTIFICATION AUDITS

Certificate renewal audits are conducted prior to the expiration of their validity period (3 years).