Certification Procedure for Medical Device MS			
Standard or Certification scheme:	**ISO 13485:2016**	**Accreditation Standard:**	**ISO 17021-1:2015**

Certification Cycle:

The certificate is valid for three years. To maintain the validity of the certificate, annual surveillance audits shall be carried out. Before the expiration date of the certificate, a recertification audit is conducted in order to renew the validity of the certificate for the next three year cycle.

Audit planning and time table. Surveillance audit process has to be completed annually, with due date the date of the certification decision after the Initial Certification audit. Correspondingly the re-certification audit process has to be completed within the same time frame. Example:

Certification Decision	**1st Surveillance audit**	**2nd Surveillance**	**Re-certification audit**
15/7/2020	*15/7/2021*	*15/7/2022*	*15/7/2023*

In case of exceeding time limits certificate is suspended for six months and after this period finally withdrawn

Audit Conduction Procedure:

The certification procedure is conducted in two stages:

Stage 1: Main purpose of stage 1 is to evaluate the organization's documentation and specifically

- ✔ The operation license and the legalization documents of the products (eg CE mark, marketing authorization from the National Agency for Medicines etc)
- ✔ the existence of a documented risk analysis for the produced or supplied products, based on ISO 14971
- ✔ detailed descriptions and product specifications
- ✔ detailed descriptions for production and management of products and technical and / or validation practices
- ✔ establishment and implementation of traceability
- ✔ vigilance and communication procedures with all interested parties
- ✔ procedure and system for the withdrawal and recall of products
- ✔ the design of the MS in accordance with the quality policy
- ✔ if the implementation of the MS provides data for stage 2 audit
- ✔ if the internal audit meets the requirements of the standard
- ✔ Whether management reviews cover the continued suitability, adequacy and effectiveness of the MS
- ✔ the adequacy of documentation in accordance with the requirements
- ✔ the means by which continuous improvement occurs (markers, quality objectives)
- ✔ the existence of regulations, legislation, any agreements with the authorities
- ✔ Any files based on which the organization estimates its compliance with the regulations and legislation

Stage 2: During the onsite audit the following topics are evaluated:

- ✔ the implementation and effectiveness of the management system,
- ✔ infrastructure and storage equipment,
- ✔ the implementation of the quality policy,
- ✔ compliance with legal requirements relating to the product,

	✔ the application of all the procedures laid down by the standard and by the company's quality system ✔ all records laid down by the standard and by the company's quality system **Certification scope** The scope of certification is precisely documented. Part of processes, products or services (unless allowed by regulatory authorities) are not excluded from the scope of certification when those processes, products or services have an influence on the safety and quality of products. **Multi-site sampling** Design, development and manufacturing sites **cannot** be sampled. **Surveillance – Recertification** During the onsite surveillance – recertification audit the following topics are evaluated: ✔ restoration of the observations and / or non-conformities of the previous audit ✔ all the topics mentioned at stage 2 of the certification audit ✔ a review of actions taken for notification of adverse events, advisory notices and recalls.
Audit Evaluation Criteria / Characterization of Non Conformities:	**1:** Full conformity **2:** (O): Points of Improvement, the effectiveness of the corrective actions are evaluated during the next audit **3:** Non Conformity (-ies): Correction through the submission of Documents **4:** Non Conformity (-ies): Correction through Re-audit
Time allowed to close Non Conformities:	Certification Audit: 2 months after the completion of stage 2. Surveillance Audit: 2 months after the date of the audit or no later than the due date of the certification decision. Recertification Audit: 2 months after the date of the audit or no later than the due date of the certification decision.
Audit Documentation:	1. Application 2. Offer 3. Selection and Approval of Auditors / Calculation of mandays form 4. Audit program 5. Audit questionnaire 6. Audit report 7. Release of audit documentation form 8. Certification text form

The following list provides a key-word-based overview of the changes made to this QM document over time.

Revision	Date	Change	Training
00	DD.MM.YYYY	Initial draft	Yes/no