Total Quality. Assured.

PROCESSES FOR GRANTING, REFUSING, MAINTAINING, RENEWING, SUSPENDING, RESTORING OR WITHDRAWING CERTIFICATION OR EXPANDING OR REDUCING THE SCOPE OF CERTIFICATION

At all times, The Medical Notified Body shall be able to confirm the status of any certification as valid, suspended, withdrawn, or reduced in scope.

Upon completion of each certification activity, Intertek personnel shall conduct an independent and impartial review of the conformity assessment activities to evaluate the outcomes of the audit and technical documentation processes including related recommendations of the auditing and technical documentation team prior to issuing certification. Based on the audit and technical documentation assessment conclusions, Intertek's certification authority makes a decision to grant, maintain, renew and/or restore certification if there is sufficient objective evidence of conformity; or to refuse, suspend or withdraw certification if there is not sufficient evidence of conformity or significant evidence of nonconformity. Certification cannot be issued if the organisation persistently or seriously fails to meet certification requirements, such as lack of implementation of effective corrective actions, due to product safety issues, default of payment, or breach to contractual agreements.

The reviewer may also decide to include expansion or reduction of the scope of certification.

Granting certificate(s)

The decision to grant a certificate is made by Intertek's Certification Authority once all the criteria's have been met to sufficiently address the completeness and fulfilment of applicable requirements.

Refusal of certificate(s)

The decision to refuse a certificate is made by Intertek's Certification Authority due to incomplete conformity assessment activity.

Maintain certification and renewing of certificate(s)

The Medical Notified Body maintains certification based on demonstration that the client continues to satisfy the requirements of the management system standard and applicable regulations.

Suspension of certificate(s)

The suspension of a certificate implicates the temporary status of a client's certification is temporarily invalid.

The decision to suspend a certification should be assessed and decided by the Intertek' certification authority.

Suspension of certification may be done in the following cases:

- The certified client's management system has failed to meet certification requirements, including requirements for the effectiveness of the management system.
- The certified client does not allow surveillance or recertification audit or technical documentation assessments to be conducted at the required frequencies.
- In case of not applying applicable requirements that has changed.

- Product safety issues or lack of insufficient clinical evidence.
- Misuse of certification mark.
- In case of providing false information or document during the conformity assessment activities performed by Intertek Medical Notified body.
- Violate contract or agreement of certification.
- Violate contract or agreement of certification.

A decision letter claiming the reason for suspension shall be sent to the client including the criteria's to be met to reinstate the certificates followed by the date of such accomplishment.

Withdrawing of certification

Intertek Certification Authority shall withdraw certification in case failure to resolve the issues that have resulted in the suspension within six month or if the certified client has voluntarily requested for withdrawal.

Restoring of Certificate(s)

The decision to reinstate a certificate is made by Intertek's Certification Authority post suspension activities if all the criteria has been met.

If the reason for the initial suspension has been rectified within the reported timeframe and with documented evidence, then an investigation will be initiated to attain approval for the re-instatement of the certificate.

Following expiration of certification, the certification body can restore certification within 6 months provided that the outstanding activities are completed, otherwise at least a stage 2 audit and or a review of technical documentation shall be conducted. The effective date on the certificate shall be on or after the decision and the expiry date.

Upon approval, a formal letter shall be generated and sent to the client confirming re-instatement of the certificate.

Suspensions, withdrawal, restoring, refusal or granting of Certificate(s) shall reported in the Eudamed database by Intertek Medical Notified Body if related to MDR EC certificates and once the Eudamed is in place.

Expanding or Reducing the scope of certification

Intertek Notified Body shall, in response to an application for expanding the scope of a certification already granted, undertake a review of the application and determine any conformity assessment activities necessary to decide whether or not the extension may be granted.
Our certification process for MDR and ISO 13485 can be downloaded on our website www.intertek.com/assurance/mdr.

For the MDD certification please refer to the below important information:

Transitional provision under Article 120 of the (EU) 2017/745 (MDR) with regard to devices covered by certificates according to MDD

Article 120(2) and 120(3) of the Medical Device Regulation (EU) 2017/745 (MDR) states that devices which have a valid certificate issued by a notified body under the Active Implantable Medical Devices Directive 90/385/EEC (AIMDD) or the Medical Devices Directive 93/42/EEC (MDD) may be placed on the market or put into service after the date of application of the MDR under certain

conditions and no later than 26 May 2024. Conditions referred to in the first paragraph require that no significant changes in design or intended purpose of a device be performed after the date of application of the MDR.

The significant changes to be considered under MDR Article 120(3) should be based on guidance MDCG 2020-3. Assessments by the Notified Body should be made on a case-by-case basis. The principles outlined in MDCG 2020-3 can be applied also for class I devices requiring the involvement of a notified body for the first time. It is expected that manufacturers adjust the change notification procedures, i.e. the provisions to inform the notified body on changes. The adjusted procedures will be subject to notified body assessment within their surveillance activities according to MDR Art. 120(3).

Changes to Directive certificates

It is important to highlight that no issuing of new MDD/AIMDD certificates, including modified, amended or supplemented certificates, is allowed under MDR Article 120(3). In particular, if the manufacturer wishes to make a "significant change in design or intended purpose" under MDR Article 120(3), the implementation of such a change would prevent the manufacturer from continuing to place that device on the market under the Directives. Changes will be verified by the notified body as part of the surveillance activities or following a manufacturer's submission for prior approval. The outcome of this verification will determine whether a certificate in accordance with AIMDD/MDD remains valid according to Article 120 MDR.

For any enquiry related to MDD please contact: medtechsweden@intertek.com

For any enquiry related to MDR or ISO13485 please contact: IMNB@intertek.com