# Process description for certification public

## Introduction

RISE Medical Notified Body (RISE MNB) conducts conformity assessments for medical devices in accordance with Regulation (EU) 2017/745 on medical devices (MDR) as well as offers ISO 13485 certification for the quality management system of medical devices. This process describes how RISE MNB's assessment takes the customer from an application to an issued certificate. The assessment is conducted by auditors and medical device experts who are employed or contracted by RISE MNB. These auditors and medical experts are not involved in the assessment if their impartiality could be questioned.

## Conformity assessment

### Pre-application

1. **Pre-application**: Customers submit information for an initial assessment via an pre-application inquiry. RISE MNB preliminarily assesses that the product is a medical device, has the correct risk class in relation to the selected appendix and that it is included in RISE MNB's scope[1]. The pre-application is accepted in Swedish or English and communication with the manufacturer can be done in either Swedish or English as agreed.
2. **Quotation**: After approval of the pre-application, RISE MNB sends a quote for the assignment. The quoted price and scope of the assignment may need to be revised during the assignment due to results that might emerge, for example changed conditions.

### Application

1. **Application and agreement:** After approval of the quotation, customers submit a formal application, which must be in writing and accompanied by information provided on the intended application form. RISE MNB sends a conformity assessment agreement that is signed by the customer. RISE MNB then carries out a final assessment of the application. If the application is accepted by RISE MNB, an order confirmation is sent, and the assignment can begin according to the agreed timetable. Approximately 3 months prior to the start of the activities, RISE MNB requests documentation regarding the customer's quality management system, the technical documentation including clinical evaluation, which the customer must submit with a response time of <30 days.
2. **Planning**: Depending on the chosen annex and risk class of the device, RISE MNB plans the assessment activities, such as on-site audits at the manufacturer's premises and technical documentation assessment including clinical evaluation.

### Initial conformity assessment

1. **Stage 1 audit:** An initial audit is conducted by the lead auditor to ensure that the quality management system is complete in accordance with the application. The auditor verifies that the quality management system fulfils the requirements of MDR and ISO 13485 as applicable. The date and time of the audit are usually agreed between the current lead auditor and the manufacturer's representative. During a stage 1 audit, no non-conformities are issued, but the lead auditor makes comments in the audit report which should be considered for the stage 2 audit.
2. **Assessment of technical documentation:** The device's technical documentation including clinical evaluation is reviewed and assessed by the product reviewer and clinical expert based on the chosen procedure in the MDR and the device's risk class. The initial assessment of the technical documentation including clinical evaluation must be finalized before the stage 2 audit is conducted.

[1] We recommend that the manufacturer checks whether the devices are included in the RISE MNB designation as a notified body via the European Commission's NANDO database.

3 **Stage 2 audit:** Performed by the lead auditor to ascertain that the manufacturer's quality management system complies with the relevant MDR and ISO 13485 provisions as applicable.

4 **Reporting and management of nonconformities:** For each audit and review of technical documentation, a report is written up containing the results of the review, including nonconformities, conclusions, and recommendations. The customer provides a root cause analysis, corrections, and corrective actions for the nonconformities within the timeframes specified in the report. Nonconformities are classified as minor or major. Each member of the assessment team manages and responds to the customer regarding the corrective measures proposed by the manufacturer. Detailed instructions on how the manufacturer should respond to RISE MNB concerning nonconformities are described in "Submission of responses to non-conformities to RISE MNB".

## Final review, decision and certification

1 **Final review:** After the stage 1, stage 2 audits and the assessment of technical documentation, RISE MNB carries out a final review of the assignment including reports and actions.

2 **Decision**: After an approved final review, RISE MNB takes a decision regarding certification. Decisions are also taken on an ongoing basis during the certificate's validity period as part of surveillance activities. A decision can result in granting, denying, maintaining, renewing, suspending, restoring or withdrawing certification, as well as expanding or reducing the scope of certification.

3 **Certification:** If the quality management system and the device comply with the applicable requirements, RISE MNB will issue a certificate in English. The certificate is valid for a maximum of five years for MDR and three years for ISO 13485, provided that all the conditions for certification are being met.

4 **Marking:** The holder of a valid EU certificate issued by RISE MNB may use RISE MNB's ID number as the notified body, together with the CE mark on the devices covered by the certificate.
Detailed provisions regarding the use of RISE MNB's mark are described in "Regler för användning av certifikat och märken RISE MNB" (Rules for using RISE MNB certificates and marks).

## Post-certification surveillance

1 **Surveillance audit:** After the certificate is issued, annual surveillance audits are performed to assess that the quality management system continues to fulfil the MDR and ISO 13485 as requirements as applicable. Surveillance audits can also be performed at the sites of the manufacturer's critical suppliers.

2 **Product review:** RISE MNB will request the submission of technical documentation including clinical evaluation for review according to an established plan depending on the chosen procedure and the device's risk class.

3 **Unannounced audit:** RISE MNB must conduct at least one unannounced audit during a five-year period. RISE MNB has also the right to conduct unannounced audits or surveillance audits at short notice if RISE MNB receives information about significant safety deficiencies, company changes, or device changes. An unannounced audit is conducted at the manufacturer's premises to verify that the devices and quality management system comply

with the applicable requirements of MDR. The unannounced audit can also be performed at the sites of the manufacturer's critical suppliers.

4 **Vigilance:** The customer is responsible for submitting post-market surveillance reports to RISE MNB. This applies to vigilance, serious incidents as well as field safety corrective actions on the market in accordance with the MDR. RISE MNB assesses whether existing certificates are affected.

5 **Information on significant changes:** The customer is responsible for informing RISE MNB of significant changes to their quality management system, devices, organization, etc. RISE MNB assesses whether any significant changes affect the manufacturer's compliance with applicable requirements. Regarding the MDR, the manufacturer must await prior approval from RISE MNB before implementing the planned change.

## Recertification

1 **Recertification audit:** The customer must apply to renew their certificate for a new certification period. RISE MNB conducts a recertification audit of the quality management system and also a reassessment of the technical documentation including clinical evaluation for conformity assessment under the MDR.

## Other considerations

1 **Customer feedback:** Any interested party can submit feedback, regardless of whether they are a customer of ours or have some other interest in RISE MNB's work. Such feedback should be sent to mnb@ri.se and include name, contact details (e-mail, telephone number, address), information about the assignment or service, and the reason for the feedback. RISE MNB will then register the case and appoint an administrator. The administrator will analyze the case, compile information, and make a recommendation for decisions and actions. Decisions are taken by the responsible manager who communicates to the person who filed the complaint.

2 **Complaints, or appeals:** If customers have complaints or wish to appeal a decision, it is sent to mnb@ri.se and including name, contact details (e-mail, telephone number, address), information about the assignment or service, and the reason for the complaint or appeal. RISE MNB will then register the case and appoint an independent administrator. The administrator will analyze the case, compile information, and make a recommendation for decisions and actions. Decisions are taken by the responsible manager in cases of complaints and the CEO in cases of appeals. Decisions are communicated to the person reporting the matter and other interested parties.

3 **Suspension or withdrawal of certification:** A suspension or permanent withdrawal of a certificate might be necessary for several reasons; this is assessed on a case-by-case basis. When a certificate is suspended or withdrawn, any reference to the certification in promotional materials or other publicity must cease immediately. If an EU certificate under the MDR is suspended or withdrawn, the manufacturer must not place on the market or put into service the devices covered by that certificate. A certificate can be suspended temporarily for six months. If a certificate has been suspended for more than six months, it is withdrawn permanently, and a completely new initial conformity assessment is required.

## Contact us

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