REQUIREMENT SPECIFICATION
FOR CERTIFICATION OF INDIVIDUALS:

QA/RA LEADER- MEDICAL DEVICES

CONTENTS

1 INTRODUCTION

This document is developed by the Scheme Committee for certification of individuals in medical device organisations who are responsible for the company´s regulatory compliance, hereby called QA/RA Leader(s) Medical Devices.

The purpose of this requirement specification is to define the knowledge requirements for the certification of individuals who are responsible for the regulatory compliance of the medical device organisation in accordance to current application regulations within the EU. The scope of this requirement specification is limited to the above given areas of business and is limited to making demands of regulatory competence. Evaluation of the technical skills required in the role within the specific business sector is the responsibility of each organization.

The scheme committee for the certification of QA/RA Leader for medical devices organisations consists of established actors within the Swedish medical device industry and with documented knowledge and experience within this area.

The certification is intended for persons working with Quality and Regulatory responsibilities within the medical device industry. A successfully passed exam will lead to certification as a Quality Assurance & Regulatory Assurance Leader Medical Devices. A person certified against this requirement specification related to experience and formal education will also fulfil the requirements for “Person Responsible for Regulatory Compliance” as specified in Article 15 of the Medical Device Regulation MDR (EU) 2017/745 and in vitro Diagnostic Device Regulation IVDR (EU) 2017/746.

Within the medical device industry there are high expectations on documented competence. Certification has been developed to ensure that manufacturers have knowledge in order prevent against the risk of accidents and incidents occurring as a result of their businesses or products.

This is done by evaluating the person’s competency in order to do the following:

- Understand how medical device regulations are designed and expected to be observed.
- Ensure products are in accordance with regulatory requirements before being introduced to the market.
- Maintain product safety when the product is put on the market, by working with an implemented management system, including risk management and market surveillance, which meet the requirements of the regulations.
- Have knowledge and understanding of how accident and incident reporting is supposed to work.

Within the EU there are regulations created in order to ensure that only safe medical device products that perform as intended are marketed. National competent authorities are found in all EU countries and in many others outside the EU. The regulations clearly stipulate that the company is responsible for quality. This responsibility is also channelled to the individual roles within the company, requiring clear, documented competence.

Certification of individuals as QA/RA Leader is evidence that the person has acknowledged, documented qualifications in their regulatory competence as well as knowledge about quality management within the medical device industry. The qualifications cover knowledge about and application of the applicable regulations and standards.

Furthermore, the certification is aimed at providing prerequisites for determining the appropriate competence and suitability to operate as a quality manager and/or regulatory manager in accordance with the requirements stipulated in the European regulations for medical device companies.

SBQ has together with the Scheme Committee developed this requirement document. SBQ is document owner of this requirement specification and is responsible for continuously managing the document and developing it in order to continuously ensure that the requirements reflect the current applicable requirements of the market.

2 BACKGROUND AND OBJECTIVE WITH CERTIFICATION

The requirement to show documented evidence of competence for persons working with quality and regulatory areas within the medical device industry is constantly increasing. These requirements originate both from competent authorities, customers, third party organisations and from the industry itself. These requirements are an essential part in the medical device organisation and aim to ensure that companies manage their operations in a way that ensures that the applicable regulatory requirements are met. Requirement fulfilment ensures that a product is safe for its intended use, perform as intended and that the organization has procedures for proper handling of the product during development and on the market. If the requirements are not met, the authorities may, for example, decide to withdraw the product from the market.

Certification as QA/RA Leader has been developed to ensure that people responsible for these areas (QA/RA) have sufficient and relevant competence within the subjects.

3 DEFINITIONS AND REFERENCES

3.1 DEFINITIONS

Certification:	Shall be performed by one or more certification organisations and will mean that the individual has experience and knowledge relating to the applicable requirements (Annex 1 Detailed requirements QA/RA LEADER)
Certification organisation:	A company performing the certification.
Examination:	Exam designed to verify knowledge in accordance with this requirement specification
Initial certificate:	Certificate given after the first approved certification.
Initial knowledge:	The knowledge level needed to fulfil the requirements for the initial certificate.
Proctor:	Person who monitors the examinations.
Certification Manager:	Independent person with sufficient competence to issue certificates on the basis of the overall result of the examinations.
Recertification:	Shall be performed to demonstrate that the previously certified person has maintained their level of knowledge both in theory and practice as well as kept up to date with new regulatory requirements.

3.2 REFERENCES

- Annex 1: Detailed requirements QA/RA LEADER

4 GENERAL REQUIREMENENTS FOR CERTIFICATION

Language:	English.
Type:	Initial certificate
Duration:	Five (5) years initial certificate

5 EXAMINATION

Applicants must demonstrate their knowledge in a theoretical examination, consisting of four tests. The four areas in this requirement specification are handled in each subsection. Requirements on what should be dealt with each area are included in Appendix 1 to this document. All four areas are included in the examination.

5.1 THE FOUR TESTS IN THE EXAMINATION

The four tests are divided up according to the following:

1. The EU regulatory system
2. Management system
3. Product development
4. Post-market surveillance

The test may be performed as a traditional class room test with surveillance or as a proctored online test.

5.2 TEST QUESTIONS

There are approximately 15 question for each of the four areas and all questions have two to four alternatives for answer and only one alternative is correct.

5.3 ISSUANCE OF CERTIFICATE

Certificates are issued to candidates who have achieved at least 70% of correct answers in each examination and have submitted acceptable documented practical experience.
The candidates have the right to retake each test one time if the test result is below 70%. Thereafter proof of completed training is required in order to be entitled to retake the test.

6 CERTIFICATE VALIDITY

6.1 MONITORING

Monitoring takes place in order to ensure that the certified person fulfils all requirements which the certificate requires during the duration of validity. The certificate holder shall verify what duties they had, specify hours worked and tasks. Such data must be verified by an appropriate reference. Subsequently this documentation shall be sent to the certification body for assessment and approval that the level of knowledge is maintained.

6.1.1 Special requirements on the certificate holders during the certificate validity period

It is the responsibility of the certification body to inform certificate holder about their obligations under the validity of the certificate to:

- operate professionally in the field for at least 3 of the 5 years
- always give change of address and change of employer to the certification body
- be sure to have certificate of employment when changing employer
- answer those questions posed by the certification body
- receive any information from the certification body
- be aware that insufficient competence and misuse can lead to withdrawal of certificate.

6.2 WITHDRAWAL OF CERTIFICATE

A certificate can be withdrawn if the certification body becomes aware that the certificate holder no longer fulfils the requirements for certification and does not take the required action in order to maintain the competence within a suggested timeframe
A certificate can also be withdrawn if it is misused. Misuse can be misrepresentation of the scope of the certificate, misleading marketing, and untruthful statements about certification process. Serious misuse can lead to legal action. Withdrawal can also become necessary as a result of non-professional conduct.

6.3 SPECIAL REQUIREMENTS FOR RENEWAL

A certificate is valid for five years. After five (5) years, the certificate holder is entitled to apply for a five-year extension. To receive an extension, the certificate holder must undergo screening to show that he/she has acquired the new skills required, and has maintained the older ones. The certificate holder shall have served in a relevant medical device capacity for at least 3 years of validity of the certificate and any period of absence should not exceed 1 year in duration. If there has been one or more breaks lasting more than 1 year each, then a new certification exam is required.