Raad voor Accreditatie (Dutch Accreditation Council RvA)

Specific Accreditation Protocol for Certification according to ISO 13485

Document code:	**RvA-SAP-C021-UK** **Version 5.0, 06-07-2021**

A Specific Accreditation Protocol (SAP) describes the assessment service for a specific accreditation. It should be read in conjunction with the generic RvA regulations and policy documents.
A current version of the SAP is available through the website of the RvA. (www.rva.nl).

Content

INTRODUCTION

This specific accreditation protocol should be read in conjunction with the SAP-C000; only additional deviating aspects are mentioned in this SAP. This means that paragraph numbers in this SAP are missing if the information already is in SAP-C000.

1 Relevant documents

1.1 Standard used for accreditation

- ISO/IEC 17021-1, Conformity assessment - Requirements for bodies providing audit and certification of management systems – Part 1: Requirements.

1.2 Additional standards

- ISO/IEC 17021-3, Conformity assessment - Requirements for bodies providing audit and certification of management systems - Part 3: Competence requirements for auditing and certification of quality management systems.

1.4 Additional documents (indirectly applicable)

- ISO 14971, Medical devices – Application of risk management to medical devices.
- IAF MD 8, Application of ISO/IEC 17011:2017 in the Field of Medical Device Quality Management Systems (ISO 13485)

1.5 Documents related to the conformity assessment to be carried out

Certification bodies certify against:

- ISO 13485; Medical devices - Quality management systems - Requirements for regulatory purposes.
- IAF MD 9, Application of ISO/IEC 17021-1 in the Field of Medical Device Quality Management Systems (ISO 13485)

2 Scope of accreditation

In accordance with the requirements of IAF MD 8, the scope of accreditation for ISO 13485 is granted per technical area corresponding to the directives/regulations concerning medical devices.
These have been listed in Annex 1. Please note that the Annex (in line with IAF MD 9) indicates both “Main Technical Areas” (the dots) and “Technical Areas” (the dashes).

Regulatory Authorities (like Competent Authorities in the EU) prefer a confirmation that manufacturers of Sterilized Medical Devices work according to Sterilization Standards within their quality management system. These Sterilization Standards are no quality management system standards. Interested parties expect the certifying CAB also to review the applicable quality management system requirements and confirm this in a written statement.

The policy of the RvA[1] is that reference to the applicable quality management system requirements of the Sterilization Standards can be mentioned on the ISO 13485 certificate under accreditation under conditions mentioned below.

Sterilization Standards on the scope of accreditation is possible under the following conditions:
If a CAB wants to add the quality management system requirements of a sterilization standard on the issued ISO 13485 certificate the CAB must expand their scope of accreditation with the required quality management system requirements of a sterilization standard.

1. apply for extension of the scope of accreditation using the downloaded F105 and F006-2 form on the RvA website
2. The following documents should be submitted:
   a) list of auditors/technical experts qualified for the required sterilization standards
   b) work procedures and instructions for the verification of these standards (related to the QMS-requirements)
   c) competence criteria and qualification procedure
   d) report internal audit and management review addressing this extension
   e) recent reports (minimum of three, if applicable) of an ISO 13485-client in each of the concerning Technical Areas
   f) an (estimation) of the number of clients in these Technical Areas in question
   g) an example of the certificate
3. After receipt the RvA will conduct a document review and when found according to the requirements accreditation can be granted.
4. The scope of accreditation will contain the quality management system requirements of the granted sterilization standards in table A.1.5.
5. The confirmation letter of the extension will include the confirmation that the next regular witness will be an audit in Technical Area A.1.5 Sterilization Methods for MD including one of the granted sterilization standards. This can be a regular surveillance audit (need not to be a reassessment or initial audit).

3 Accreditation assessments

3.1 Documents to be submitted

In line with the requirements of IAF MD 8:2020 (7.14.3), additional to the documents mentioned in the relevant application form and the annex to RvA-BR005, the records on the CAB to be submitted shall include concerns, opinions and feedback received from a Regulatory Authority on the performance of the CAB, pertaining to the scope of accreditation.
To enable the RvA assessment team in line with the requirements of IAF MD 8:2020 (7.6.4.1) to appraise publicly available information published by a sample of the certification body's certified manufacturers, a complete list of the certified manufacturers needs to be submitted at least a month

[1] If consensus is reached within EA or IAF on this topic, the policy of RvA will be changed accordingly.

prior to the office assessment. The list shall include the technologies, intended purpose(s) and classification(s) of the medical devices (see Annex 2).

The RvA assessment team shall assess the submitted list and the publicly available information prior to the actual assessment, hence the preparation time will be increased. The output of this appraisal will be verified during the office assessment by the RvA assessment team.

Certification bodies accredited for Main Technical Areas ‘other than specified above’ (see Annex 1) shall provide a list of medical devices and include their risk classification to the RvA. The information provided shall also include a concise statement of the intended purpose of the medical device (see Annex 3).
The technical area “Other than specified” may only be used when no other category is applicable. Risk classification of Medical Devices should be determined using appropriate regulatory sources. Examples include:

i Medical Devices Classification GHTF/SG1/N77:2012
ii (EU) 2017/745 Annex VIII Classification Rules
iii National Classification Regulations

Where the CAB is seeking accreditation for a scope, which includes non-manufacturing activities or manufacturing of parts which are not categorized or clearly associated with a finished medical device, Table 1.7 shall be used for scoping.

In addition to the scope of a medical device as specified in ISO 13485, the certification body’s choice to consider the goods or services as a medical device must be supported by official Guidelines or Specifications issued by a Regulatory Authority.

3.2 The nature and content of the assessments

In addition to the generic rules for the type and content of RvA assessments as defined in RvA-BR002, RvA-BR005 and SAP-C000, for this specific accreditation the requirements from the following table apply. The type, extent and content of the assessment depend on the requested scope of accreditation, other accreditations possibly existing and the functioning of the CAB in the past (where relevant).

Assessment method	Initial assessment	During the Accreditation cycle (1)	Scope extension (2)
Document assessment	√	√	√
On site Office assessment	√ At least one certification file and one personnel file per Technical area	√ (annually) At least one certification file and one personnel file per Main technical area during the accreditation cycle and at least one certification file per Technical area during two successive accreditation cycles	√ At least one certification file and one personnel file per Technical area
Witnessing	See policy concerning witnessing (3.2.3)	√ (annually) See policy concerning witnessing (3.2.3)	See policy concerning witnessing (3.2.3)

(1) An accreditation cycle is a timeframe of four years, starting after a decision on initial assessment or reassessment has been made; the cycle consists of regular assessments (surveillance) and the reassessment in this period

(2) Based upon the requested scope extension (form RvA-F105), the RvA will determine how the assessment of the extension will be conducted.

3.2.1 Accreditation cycle

In line with the requirements of IAF MD 8:2020 (7.9.3), the RvA surveillance and reassessment include on-site office and witness assessments and shall be conducted at least once a year. The witnessing program shall ensure, as a minimum, one audit from each of the Main Technical Areas (shown in Annex 1 of IAF MD 8) under the scope of accreditation within an accreditation cycle. The sampling for witnessing will give priority to higher risk technical areas.

3.2.2 Scope extension

The assessment by the RvA in case of an application for an additional technical area shall include at least the defined requirements for competence in that sector, records of the qualification process of auditors for that sector, and a complete certification and personnel file in that sector.

3.2.3 Policy concerning witnessing

In line with the requirements of IAF MD 8:2020 (7.4.5) the samples for witnessing of audits shall include one audit minimum in a higher risk class of the Technical Areas in each Main Technical Area (shown in Annex 1) covered under the scope of accreditation. In the selection for the witnessing of audits an appropriate national or international risk classification scheme and/or criticality of the process (e.g. Sterilization) shall be taken into account (see IAF ID 13:2017 Medical Device Nomenclature (IAF MDN) Including Medical Device Risk Classifications).

The experience of the CAB recognized for one or more medical device regulatory scheme(s), among other factors, will be considered in the witnessing schedule.

Examples of typical regulatory schemes are:

i (EU) 2017/745/746 – European MDR/IVDR Regulations

ii ASEAN Medical Device Directive (AMDD)

iii National Medical Regulations that utilize ISO 13485

Previous results of witnessing will be taken into account in the witnessing strategy.

All locations where one or more key activities (see RvA-BR003, chapter 7) are performed shall be assessed during the accreditation cycle.

In case of extension of scope, the strategy for the assessment depends on the sector and the scope already accredited. The following guidelines apply:

- In case the requested technical area is for a main technical area (i.e. in another bullet, see Annex 1) the CAB is not yet accredited for, a witness (see 3.2.3) shall be included;
  In case the requested technical area is considered to be a higher risk than the ones already accredited, a witness shall be included.

4 Specific issues for the RvA assessments

In line with the requirements 4.4.1 and 4.5.1. of IAF MD 9, the RvA assessors will check whether the CAB verifies that the client organization has evaluated statutory and regulatory compliance and has made agreements with their clients to release audit report information to regulators that recognize ISO 13485.

4.1 Initial, surveillance and re-assessments

The specific normative criteria mentioned in IAF MD 9 are applicable in addition to the requirements contained in ISO/IEC 17021-1.
During the RvA office assessments specific attention will be paid to the following clauses of IAF MD 9 which hold additional requirements:

MD 5.2 Management of impartiality
MD 7.1 Competence of personnel
MD 7.2 Personnel involved in the certification process
MD 8.1 Public information
MD 8.2 Certification documents
MD 9.1 Pre-certification activities
MD 9.2 Planning audits
MD 9.3 Initial certification
MD 9.4 Conducting audits
MD 9.6 Maintaining certification

Also, the Annexes A, B, C and D of IAF MD 9 are normative for ISO 13485 certification/accreditation.

The RvA assessment plans and reports shall refer to these requirements when they will be/have been part of the assessment.

5 Changes compared to the previous version of this document

Compared to version 4, dated 3 January 2020, the following significant changes have been made:

- 2. Scope of Accreditation Policy of RvA concerning quality management system requirements of Sterilization Standards on accredited scope of ISO 13485
- 3.1 Documents to be submitted Due to the new IAF MD 8:2020 the CAB must submit extra information prior to the assessment
- 3.2 The nature and content of the assessments. Due to the new IAF MD 8:2020 document assessment is also part of surveillance and reaccreditation assessments
- Annex 1 due to a more detailed registration of the scope of accreditation in MTA 1.5 Sterilization Methods in IAF MD8:2020 the example is extended.
- Annex 2 template for list of certified clients
- Annex 3 template for list of medical devices other than specified above

Annex 1: Example of a full scope for ISO 13485

Standard / Normative document	Certification scheme(*)
ISO 13485	Medical devices — Quality management systems — Requirements for regulatory purposes for the scopes: • 1.1 Non-active Medical Devices - General non-active, non-implantable medical devices - Non-active implants - Devices for wound care - Non-active dental devices and accessories - Non-active medical devices other than specified above • 1.2 Active (Non-Implantable) Medical Devices - General active medical devices - Devices for imaging - Monitoring devices - Devices for radiation therapy and thermo therapy - Active (non-implantable) medical devices other than specified above • 1.3 Active Implantable medical devices - General active implantable medical devices - Implantable medical devices other than specified above • 1.4 In Vitro Diagnostic Medical Devices (IVD) - Reagents and reagent products, calibrators and control materials for: Clinical Chemistry Immunochemistry (Immunology) Haematology/Haemostasis/Immunohematology Microbiology Infectious Immunology Histology/Cytology Genetic Testing - In Vitro Diagnostic Instruments and software - IVD Medical Devices other than specified above • 1.5 Sterilization Methods for Medical Devices - Ethylene oxide gas sterilization (EOG) - including applicable quality management system requirements within ISO 11135 - Moist heat - including applicable quality management system requirements within ISO 17665-1 - Aseptic processing - including applicable quality management system requirements within ISO 13408-1 - Radiation sterilization (e.g. gamma, x-ray, electron beam) - including applicable quality management system requirements within ISO 11137-1 - Low temperature steam and formaldehyde sterilization - including applicable quality management system requirements within ISO 25424 - Thermic sterilization with dry heat - including applicable quality management system requirements within ISO 20857 - Sterilization with hydrogen peroxide - Sterilization method other than specified above - including applicable requirements within ISO 14937 • 1.6 Devices incorporating/utilizing specific substances/technologies - Medical devices incorporating medicinal substances - Medical devices utilizing tissues of animal origin - Medical devices incorporating derivates of human blood - Medical devices utilizing micromechanics - Medical devices utilizing nanomaterials - Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed - Medical devices incorporating or utilizing specific substances/technologies/elements, other than specified above • 1.7 Parts and Services - Raw materials - Components - Subassemblies - Calibration services * - Distribution services - Maintenance services - Transportation services - Other services

(*) Organizations providing calibration services should be accredited to ISO/IEC 17025

Annex 2: Template for List of Certified manufacturers

List of certified manufacturers				
Certification number	Certified Manufacturer	Classification	Technology	Intended purpose

Annex 3: Template for List of medical devices other than specified above

1.1. Non-active medical devices other than specified above		
Medical device	Risk classification	Statement of the intended purpose

1.2. Active (non-implantable) medical devices other than specified above		
Medical device	Risk classification	Statement of the intended purpose

1.3. Implantable medical devices other than specified above		
Medical device	Risk classification	Statement of the intended purpose

1.4. IVD medical devices other than specified above		
Medical device	Risk classification	Statement of the intended purpose

1.5. Sterilization method other than specified above		
Medical device	Risk classification	Statement of the intended purpose

1.6. Medical devices incorporating or utilizing specific substances/technologies/elements, other than specified above		
Medical device	Risk classification	Statement of the intended purpose

1.7. Other services		
Medical device	Risk classification	Statement of the intended purpose