REF-QMS-001

Quality Manual

Document status	Version history

State: Review

Approvals	Reviewer	Status	Date	Comment
Approval		PENDING		

Change History

Page Version	Date	Comment
Current Version (v. 1)	Aug 13, 2026, 4:28 PM	QA Manager

> Texts of 4. Quality Policy and 7. Management of Processes chapters are excerpted from other pages of the QMS.
>
> **Do not make changes to insert texts in the Quality Manual but directly in the source pages.**
>
> 4-Quality Policy source page is REF-MAN-001 Quality Policy.
> 7-Management of Processes source page is SOP-QMS-004 Management of Processes.

1. Purpose and Use of the Quality Manual

This Quality Manual defines the overall structure and governance of the Quality Management System (QMS).

It is intended to:

- provide a high-level overview of the QMS
- describe how quality processes are organized and interconnected
- demonstrate alignment with applicable regulatory requirements
- serve as a reference document for internal and external audits

Target audience

This manual is intended for:

- Top Management
- process owners
- quality and regulatory personnel
- auditors (internal and external)
- business partners when relevant

How to use this manual

The Quality Manual:

- provides direct links to detailed SOPs and reference documents
- does not duplicate controlled procedures
- reflects the current approved QMS documentation

Users shall:

- consult the linked source documents for operational details
- not modify this manual directly
- apply changes only in the source SOPs and reference documents

This approach ensures:

- consistency of information
- real-time alignment with the approved QMS
- controlled document updates

2. Review of the Quality Manual

The Quality Manual is:

- reviewed periodically
- updated when significant changes occur
- aligned with organizational and regulatory evolutions

The review is performed:

- as part of Management Review meetings
- when major organizational changes occur
- when regulatory requirements evolve
- following significant audit findings

Review activities include:

- verification of continued adequacy
- confirmation of alignment with QMS processes
- validation of links to source documents

Any required updates are:

- implemented through controlled change management
- approved according to document control procedures
- communicated to relevant stakeholders

3. Scope for ISO 13485:2016

The scope of the <Name of the Company> Quality Management System is:

<Design and development, manufacture, installation, servicing, importation and/or distribution> **of** <medical devices / in vitro diagnostic medical devices / medical device software> **, intended for** <general intended-purpose or medical field> **.**

Activities within the QMS scope may be performed internally or by qualified and controlled external organizations. Outsourcing an activity does not transfer the responsibilities retained by <Name of the Company> under applicable regulatory requirements.

The Quality Management System is established in accordance with EN ISO 13485:2016 and the regulatory requirements applicable to the devices, activities, regulatory roles and markets covered by the organization.

The products, product families, regulatory roles and lifecycle status covered by the QMS are documented in REF-QMS-005 Device(s) Covered by the QMS.

The scope is determined, approved and periodically reviewed in accordance with QMS-PROC-1.2 Determination and Review of the QMS Scope.

Non-applicable requirements

The following ISO 13485 requirements are considered non-applicable based on the activities performed by the organization and the nature of the medical devices covered by the QMS:

ISO 13485 clause	Requirement	Justification for non-applicability
<Clause>	<Requirement>	<Documented justification>
<Clause>	<Requirement>	<Documented justification>
<Clause>	<Requirement>	<Documented justification>

The complete Quality Manual is included in ReadySet

ISO 13485 QMS framework for Confluence – azbc.be