[Organization logo]

[Organization name]

Commented [13A1]: All fields in this document marked by square brackets [ ] must be filled in.

QUALITY MANUAL

Code:	
Version:	0.1
Created by:	
Approved by:	
Date of version:	
Signature:	

Commented [13A2]: Adapt to the existing practice in organization.

Distribution list

Commented [13A3]: This is only necessary if document is in paper form; otherwise, this table should be deleted.

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Change history

Date	Version	Created by	Description of change
	0.1	13485Academy	Basic document outline

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1. About organization

1.1. Organizational structure

Commented [13A4]: Adapt to organization needs.

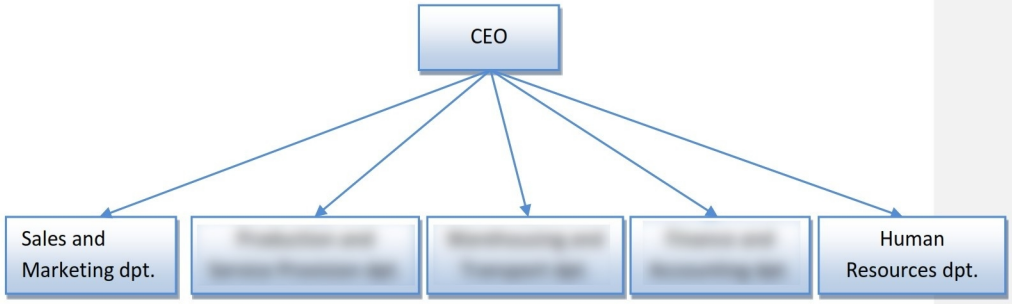

Figure 1: Organizational chart

2. Purpose, scope and users

The quality manual documents the quality management system of [organization name] and demonstrates the capability of [organization name] to continuously provide products and services

Commented [13A5]: If Quality Management System is applied only to part of organization, name that part of organization.

Commented [13A6]: Please write the scope of your Quality Management System that will also be written on the certificate.

The QMS implemented in [organization name] is in compliance with the requirements of the MDR.

Commented [13A7]: Delete this if it is not applicable to your company.

2.1. Exclusions

Commented [13A8]: Exclusions can be made only from clause 8 and clause 7.1.5 of ISO 9001:2015 standard. Name the clauses excluded from QMS and provide justifications for exclusions.

Commented [13A9]: Exclusions can be made only from clause 7 ISO 13485:2016 standard. Name the clauses excluded from QMS and provide justifications for exclusions.

- [clause] – [justification]

Commented [13A10]: Delete if your organization hasn't implemented ISO 9001:2015.

Commented [13A11]: Please include the clause of the standard; then you can exclude from your QMS.

Commented [13A12]: Please include justification for why you have excluded this clause and why you consider it to not be applicable for your company.

3. Terms and Definitions

For the purpose of this Quality Manual, [organization name] references the terms and definitions

Commented [13A13]: Please include the name of your company.

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4. Quality Management System

4.1. General requirements

In order to function effectively, [organization name] adopted a process approach by:

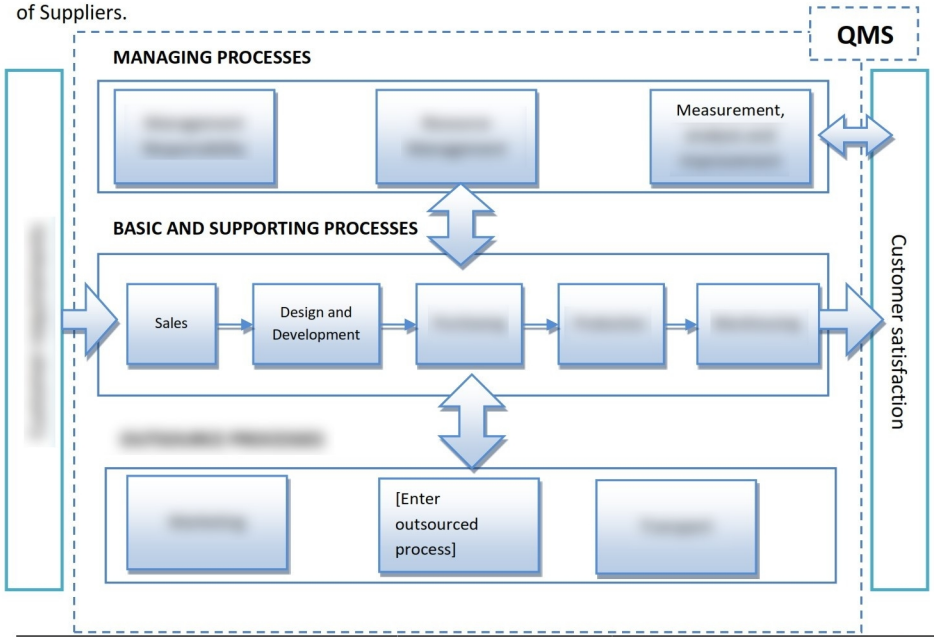
- [illegible]
- [illegible]
- Ensuring availability of resources and information necessary for support of execution and monitoring of processes, described in chapter 6 of this Quality Manual
- [illegible]
- [illegible]

[Organization name] may choose to outsource a process and must manage outsourced processes when:

- [illegible]
- [illegible]

Commented [13A14]: E.g. for commercial reasons.

Control of outsourcing processes is executed according to Procedure for Purchasing and Evaluation of Suppliers.



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4.2. Document requirements

4.2.1. General

[Organization name] documented the Quality Management System by:

- Quality Policy
- Quality Manual
- Procedures
- Records

Commented [13A15]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit folder "02_Quality_Policy".

4.2.2. Quality manual

A global description of the structure and way of functioning of the quality management system in [organization name] are given in the Quality Manual, detailed descriptions are given in referring procedures.

A Management Representative creates the Quality Manual, which is approved by [job title]. The Quality Manual is periodically reviewed by [job title] at least once a year.

Commented [13A16]: E.g. CEO

Commented [13A17]: E.g. CEO

The Quality Manual is delivered on request to customers, certification bodies or third parties with approval of [job title] as an UNCONTROLLED COPY.

Commented [13A18]: E.g. CEO

The original Quality Manual is kept by the Management Representative.

4.2.3. Medical device file

[Job title] must ensure that a medical device file exists for each medical device type or medical device family. This file demonstrates conformity to the requirements of the International Standard and compliance with all applicable regulatory requirements.

Commented [13A19]: Adapt to organization practice. E.g. CEO

4.2.4. Control of documents

[Organization name] controls documents required by the ISO 13485:2016 standard, documents which the organization determined as necessary and external documents according to Procedure for Document and Record Control.

Commented [13A20]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit folder "03_Quality_Manual".

4.2.5. Control of records

[Organization name] controls records to provide evidence of conformance with requirements and about the functioning quality management system according to Procedure for Document and Record Control.

5. Management responsibility

5.1. Management commitment

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Top-level management demonstrates its commitment to the development and application of the

- Informing employees of [organization name] about the importance of meeting customer
- achievement
-

5.2. Customer focus

Top-level management of [organization name] ensures that customer requests are determined and

5.3. Quality policy

Top-level management of [organization name] defined the Quality Policy as a separate document.

5.4. Planning

5.4.1. Quality objectives

separate document. Objectives must be measurable and aligned with the Quality Policy.

5.4.2. Quality management system planning

Regularly performed management review is the basic means of planning the QMS. Special attention

5.5. Responsibility, authority and communication

5.5.1. Responsibility and authority

Top-level management defines responsibilities through QMS procedures and [titles of documents].

Commented [13A21]: Name other documents that define

5.5.2. Management representative

[Job title] appoints [Name of employee] as Management Representative and assigned him

Commented [13A22]: E.g. CEO

- nonconformities and possibilities for improvement

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- Raising awareness of employees about the importance of meeting customer requests by
- [illegible]

5.5.3. Internal communication

Internal communication is performed directly, by mail, intranet, email and phone.

Commented [13A23]: Adapt to organization practice.

5.6. Management review

Top-level management of [organization name] conducts regular reviews of the QMS, at least once a [illegible]

[illegible] reviews the organization's Quality Management System at documented planned intervals to ensure its continuing suitability, adequacy, and effectiveness.

Commented [13A24]: E.g. CEO; management representative

6. Resource management

6.1. Provision of resources

Top-level management of [organization name] is responsible for provision of planned resources in [illegible]

6.2. Human resources

[illegible] competence, education, skills and experience according to Procedure for Human Resources.

Commented [13A25]: E.g. CEO, Human Resources Manager

Commented [13A26]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit folder "04_Human_Resources".

6.3. Infrastructure

[Organization name] provided and maintains necessary infrastructure for executing processes [illegible]

[illegible] Procedure for Equipment Maintenance and Measuring Equipment.

6.4. Work environment and contamination control

[Job title] ensures that the working environment and contamination control meets the requirements [illegible]

Commented [13A27]: If there are no specific requirements for [illegible]

Commented [13A28]: E.g. Production Manager, QA Manager

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7. Product realization

7.1. Planning of product realization

[Job title] is responsible for planning and developing processes needed for product realization [redacted].

7.2. Customer-related processes

[Job title] appoints persons responsible for determining and reviewing requests for product and [redacted].

7.3. Design and development

[redacted] and development and project management according to Procedure for Design and Development.

7.4. Purchasing

[redacted] Procedure for Purchasing and Evaluation of Suppliers.

7.5. Production and service provision

[Organization name] defined activities of planning and executing the product realization process [redacted] processes are provided according to Procedure for Production and Service Provision and Warehousing Procedure.

[redacted] is carried out according to Procedure for Production and Service Provision.

[redacted] Provision and Procedure for Sterile Medical Devices.

[redacted] Management System and production and service provision are described within Procedure for Software Validation.

Commented [13A29]: This can be excluded from QMS in cases [redacted]

Commented [13A30]: Adapt to organization practice. E.g. Production Manager

Commented [13A31]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit folder "11_Production_and_Service_Provision".

Commented [13A32]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit folder "06_Risk_Management".

Commented [13A33]: This can be excluded from QMS in case of catalogue sales, TV shop, etc.

Commented [13A34]: Adapt to organization practice. E.g. Sales Manager

Commented [13A35]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit folder "07_Sales".

Commented [13A36]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit folder "08_Customer_Complaints_and_Feedback".

Commented [13A37]: Delete if organization doesn't perform design and development process or if it's an outsourced process.

Commented [13A38]: E.g. CEO, top management representative.

Commented [13A39]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit folder "09_Design_and_Development".

Commented [13A40]: This can be excluded from QMS in cases when organization performs only small procurements that doesn't significantly affect its business, e.g. legal office, consulting agency, etc.

Commented [13A41]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit folder "10_Purchasing_and_Evaluation_of_Suppliers".

Commented [13A42]: It is possible to exclude the following clauses from 7.5:
[redacted]

Commented [13A43]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit folder "11_Production_and_Service_Provision".

Commented [13A44]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit folder "14_Warehousing".

Commented [13A45]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit folder "12_Sterilization".

Commented [13A46]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit folder "13_Software_Validation".

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7.6. Control of monitoring and measurement

[Organization name] identified processes where measurements are conducted to demonstrate [illegible] Maintenance and Measuring Equipment.

Commented [13A47]: This can be excluded in cases when [illegible]

Commented [13A48]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit folder "17_Equipment_Maintenance".

8. Measurement, analysis and improvement

8.1. General

[illegible]

[Organization name] identifies required statistical techniques and maintains procedures to [illegible]

Commented [13A49]: Adapt to organization.

[illegible] and test results are recorded in electronic databases and tracked.

Individual employee performance is tracked and recorded as part of production performance.

8.2. Monitoring and measurement

[illegible] appropriate action when necessary.

8.2.1. Feedback

[Job title] gathers and monitors information relating to whether the organization has met customer [illegible] Complaints.

Commented [13A50]: Adapt to organization practice. E.g. Sales Manager

8.2.2. Complaint handling

[illegible]

8.2.3. Reporting to regulatory authorities

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Reporting to regulatory authorities in [Organization name] is implemented according to Procedure for Adverse Event Investigation and Reporting.

Commented [13A51]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit folder "16_Adverse_Event_Investigation".

8.2.4. Internal audit

[Organization name] conducts internal audits in planned intervals to demonstrate conformance and effectiveness of the Quality Management System according to Procedure for Internal Audit.

Commented [13A52]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit folder "20_Internal_Audit".

8.2.5. Monitoring and measurement of processes

Effectiveness of product realization processes is monitored and measured through parameters for every identified process defined in Matrix of Key Process Indicators.

Commented [13A53]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit folder "23_Management_Review".

8.2.6. Monitoring and measurement of product

Product characteristics are measured and monitored throughout the manufacturing process, to ensure the product meets established requirements. Evidence of conformity with the acceptance criteria is maintained, and electronic records identify inspection and test activities according to Procedure for Production and Service Provision.

Commented [13A54]: Adapt to organization practice.

8.3. Control of nonconforming product

[Organization name] handles non-conforming product in a way that prevents its further use or delivery, according to Procedure for Control of Non-Conforming Product.

Commented [13A55]: Requirement 8.3.4 can be "not applicable" if there is no possibility to make rework after the medical device is released.

Commented [13A56]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit folder "15_Nonconformities".

8.4. Analysis of data

By systematic gathering, processing and analysing of data, [organization name] evaluates the effectiveness of the organization related to defined plans and objectives and identifies areas for improvement defined in Procedure for Data Analysis.

Commented [13A57]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit folder "22_Data_Analysis".

8.5. Improvement

8.5.1. General

[Organization name] is committed to the continual improvement of the quality management system. This is accomplished through the use of the quality policy, quality objectives, analysis of quality data, audit results, corrective and preventive actions, and management reviews.

8.5.2. Corrective action

[Organization name] has established a corrective action system to investigate and document the root cause and actions to correct internally and externally reported nonconformities. Corrective actions are assigned to a responsible individual and tracked by number and completion date according to Procedure for Corrective and Preventive Actions.

Commented [13A58]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit folder "21_Corrective_and_Preventive_Action".

8.5.3. Preventive action

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[Organization name] has established a preventive action system to report, investigate and prevent potential nonconformities. The preventive action system emulates the corrective action system.

The preventive actions taken will be appropriate to the effects of the potential problems according to Procedure for Corrective and Preventive Actions.

[job title]
[name]

_____

[signature]

Commented [13A59]: Only necessary if the Procedure for Document and Record Control prescribes that paper documents must be signed.

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