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Medical devices — Quality management systems — Requirements for regulatory purposes

Dispositifs médicaux — Systèmes de management de la qualité — Exigences à des fins réglementaires

ICS: 11.040.01; 03.120.10

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2. www.iso.org/directives

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

The committee responsible for this document is ISO/TC 210, Quality management and corresponding general aspects for medical devices.

This third edition cancels and replaces the second edition (ISO 13485:2003), which has been technically revised. Details of the changes between the second and this third edition of this Standard are described in Annex A.

This edition of ISO 13485 addresses quality assurance of product, customer requirements, and other elements of quality management systems for regulatory purposes.

0 Introduction

0.1 General

This International Standard specifies requirements for a quality management system that can be used by an organization involved in one or more stage(s) of the life-cycle of a medical device including the design and development, production, storage and distribution, installation or servicing of medical devices, and the design, development, or provision of associated activities (e.g. technical support). The requirements in this standard may also be used by suppliers or other external parties providing product (e.g., sterilization services, calibration services, distribution services) to such organizations. Such a supplier or external party may voluntarily choose to conform to the requirements of this standard or may be required by contract to conform.

Several jurisdictions have regulatory requirements for the application of quality management systems by organizations with a variety of roles in the supply chain for medical devices. Consequently, this standard expects that the organization:

- identifies its role(s) under applicable regulatory requirements,
- identifies the regulatory requirements that are applicable for its activities under these roles, and
- incorporates these applicable regulatory requirements within its quality management system.

This International Standard can also be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer and regulatory requirements applicable to the quality management system and the organization's own requirements. It is emphasized that the quality management system requirements specified in this International Standard are complementary to the technical requirements for products that are necessary to meet customer and applicable regulatory requirements for safety and performance.

The adoption of a quality management system is a strategic decision of an organization. The design and implementation of an organization's quality management system is influenced by:

a) its organizational environment, changes in that environment, and the risks associated with that environment;
b) its varying needs;
c) its particular objectives;
d) the products it provides;
e) the processes it employs;
f) its size and organizational structure; and
g) applicable regulatory requirements.

It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.

There is a wide variety of medical devices and some of the particular requirements of this International Standard only apply to named groups of medical devices. These groups are defined in Clause 3.

0.2 Process approach

This International Standard is based on a process approach to quality management.

Any activity that receives input(s) and converts them to output(s) can be considered as a process. Often the output from one process directly forms the input to the next process.

For an organization to function effectively, it has to identify and manage numerous linked processes. The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management to produce the desired outcome, can be referred to as the "process approach."

When used within a quality management system, such an approach emphasizes the importance of:

a) understanding and meeting requirements,
b) considering processes in terms of added value,
c) obtaining results of process performance and effectiveness, and
d) improving processes based on objective measurement.

0.3 Relationship with ISO 9001

While this is a stand-alone standard, it is based on, and follows the format of, ISO 9001:2008 for the convenience of users in the medical device sector.

0.4 Compatibility with other management systems

This International Standard does not include requirements specific to other management systems, such as those particular to environmental management, occupational health and safety management, or financial management. However, this International Standard enables an organization to align or integrate its own quality management system with related management system requirements. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that complies with the requirements of this International Standard.

Medical devices – Quality management systems – Requirements for regulatory purposes

1 Scope

1.1 General

This International Standard specifies requirements for a quality management system that can be used by an organization involved in one or more stages of the life-cycle including the design and development, production, storage and distribution, installation, or servicing of a medical device and the design, development or provision of associated activities (e.g. technical support). The quality management system of the organization demonstrates the ability to consistently meet customer and applicable regulatory requirements. It may also be used by suppliers or external parties that provide goods and quality management system related services to such organizations.

The main objective of this International Standard is to facilitate global alignment of appropriate regulatory requirements for quality management systems applicable to organizations providing medical devices. As a result, it includes some particular requirements for medical devices and excludes some of the requirements of ISO 9001:2008 that are not appropriate as regulatory requirements. Because of these exclusions, organizations whose quality management systems conform to this International Standard cannot claim conformity to ISO 9001:2008 unless their quality management system conforms to all the requirements of ISO 9001:2008.

1.2 Application

All requirements of this International Standard are specific to organizations regardless of their type or size.

Wherever requirements are specified as applying to medical devices, the requirements apply equally to associated services as supplied by the organization.

The processes required by this International Standard, which are applicable to the medical device(s), but which are not performed by the organization, are the responsibility of the organization and are accounted for in the organization's quality management system by monitoring, maintaining, and controlling the processes.

If applicable regulatory requirements permit exclusions of design and development controls, this can be used as a justification for their exclusion from the quality management system. These regulatory requirements can provide alternative arrangements that are to be addressed in the quality management system. It is the responsibility of the organization to ensure that claims of conformity with this International Standard reflect exclusion of design and development controls.

If any requirement(s) in Clauses 6, 7 or 8 of this International Standard is (are) not applicable due to the activities undertaken by the organization or the nature of the medical device(s) for which the quality management system is applied, the organization does not need to include such a requirement(s) in its quality management system. For the clauses that are determined to be not applicable, the organization documents justification as described section 4.2.2.

In this International standard the following terms or phases are used in the context described below:

- When a requirement is qualified by the phrase 'as appropriate', it is deemed to be 'appropriate' unless the organization can justify otherwise. A requirement is considered 'appropriate' if it is necessary for:
    - the product to meet requirements;
    - the organization to carry out corrective action; or
    - the organization to manage risks.
- When a requirement is required to be 'documented', it is also required to be established, implemented and maintained.
- When the term 'risk' is used, the application of the term is within the scope of this International standard and pertains to:
    - the safety or performance requirements or
    - meeting applicable regulatory requirements.
- When the term 'product' is used, it can also mean 'service'. Product applies to outputs that are intended for, or required by, a customer, or any intended output resulting from a product realization process.
- When the term 'regulatory requirements' is used, it encompasses statutory, regulatory and legal requirements. The application of the term 'regulatory requirements' is limited to requirements for the quality management system and the safety or performance of the medical device.
- Information marked "NOTE" is for guidance in understanding or clarifying the associated requirement.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9000:2005, Quality management systems — Fundamentals and vocabulary

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000 together with the following apply. The following definitions should be regarded as generic, as definitions provided in applicable regulatory requirements can differ slightly and take precedence.

3.1
advisory notice
notice issued by the organization, subsequent to delivery of the medical device, to provide supplementary information or to advise what action should be taken in the:

- use of a medical device,
- modification of a medical device,
- return of the medical device to the organization that supplied it, or
- destruction of a medical device

NOTE to entry: Issuance of an advisory notice might be required to comply with applicable regulatory requirements.

3.2
authorized representative
any natural or legal person who has received a documented mandate from a manufacturer to act on his behalf with respect to applicable regulatory requirements in (a) specified jurisdiction(s)

3.3
clinical evaluation
assessment and analysis of clinical evidence pertaining to a medical device to verify the clinical safety and performance of the device when used as intended by the manufacturer

3.4
complaint
written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, usability, safety or performance of a medical device that has been released from the organization's control or a service that affects the use of such medical devices

3.5
distributor
any natural or legal person in the supply chain who, on their own behalf, furthers the availability of a medical device to the end user. [SOURCE: GHTF/SG1/N055, definition 5.3]

Note 1 to entry: More than one distributor may be involved in the supply chain.

Note 2 to entry: Persons in the supply chain involved in activities such as storage and transport on behalf of the manufacturer, importer or distributor, are not distributors under this definition.

3.6
implantable medical device
medical device intended to:

- be totally or partially introduced into the human body or a natural orifice, or
- replace an epithelial surface or the surface of the eye, and

is intended to remain after the procedure for at least 30 days, and which can only be removed by medical or surgical intervention

3.7
importer
any natural or legal person with responsibility to first make a medical device manufactured in one jurisdiction available in another specified jurisdiction

Note to entry: A distributor might also act as an importer where it is the first recipient of product from the manufacturer in a particular country.

3.8
labelling
written, printed, graphic or electronic information:

- affixed to a medical device or any of its containers or wrappers,
- accompanying a medical device, or
- provided for a medical device by other means

related to the identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents

NOTE to entry: Applicable regulatory requirements refer to "labelling" as "information supplied by the manufacturer." This could include advertising, or marketing information.

3.9
life-cycle
all phases in the life of a medical device, from the initial conception to final decommissioning and disposal. [SOURCE: ISO 14971:2007, definition 2.7]

3.10
manufacturer
any natural or legal person with responsibility for design or manufacture of a medical device with the intention of making the medical device available for use, under their name; whether or not such a medical device is designed or manufactured by that person or on their behalf by another person(s)

Note 1 to entry: The definition of the "medical device manufacturer" differs from nation to nation and region to region. The organization needs to understand how the definition in the Standard will be interpreted in light of regulatory definitions for "medical device manufacturer" or equivalent term in the various nations and regions in which its medical devices are sold.

Note 2 to entry: This 'natural or legal person' has ultimate legal responsibility for ensuring compliance with applicable regulatory requirements for the medical device in the countries or jurisdictions where it is intended to be made available or sold, unless this responsibility is specifically imposed on another person by the Regulatory Authority (RA) within that jurisdiction.

Note 3 to entry: The manufacturer's responsibilities are described in applicable regulatory requirements. These responsibilities might include meeting both pre-market requirements and post-market requirements, such as adverse event reporting and notification of corrective actions.

Note 4 to entry: 'Design or manufacture', as referred to in the above definition, may include specification development, production, fabrication, assembly, processing, packaging, repackaging, labelling, relabelling, sterilization, installation, or remanufacturing of a medical device; or putting a collection of medical devices, and possibly other products, together for a medical purpose.

Note 5 to entry: Any person who assembles or adapts a medical device that has already been supplied by another person for an individual patient, in accordance with the instructions for use, is not the manufacturer, provided the assembly or adaptation does not change the intended use of the medical device.

Note 6 to entry: Any person who changes the intended use of, or modifies, a medical device without acting on behalf of the original manufacturer and who makes it available for use under his own name, should be considered the manufacturer of the modified medical device.

Note 7 to entry: An authorized representative, distributor or importer who only adds its own address and contact details to the medical device or the packaging, without covering or changing the existing labelling, is not considered a manufacturer.

Note 8 to entry: To the extent that an accessory is subject to the applicable regulatory requirements of a medical device, the person responsible for the design or manufacture of that accessory is considered to be a manufacturer.

[Based on GHTF/SG1/N055:2009, definition 5.1].

3.11
medical device
any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices, or
- providing information for medical purposes by means of in vitro examination of specimens derived from the human body

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

NOTE to entry: Products which might be considered to be medical devices in some jurisdictions but not in others include:

- disinfection substances,
- aids for persons with disabilities,
- devices incorporating animal or human tissues,
- devices for in-vitro fertilization or assisted reproduction technologies.

[SOURCE: Based on GHTF/SG1/N071 2012, definition 5.1]

3.12
performance evaluation
assessment and analysis of data to establish or verify the ability of an in vitro diagnostic medical device to achieve its intended use

3.13
post market surveillance
systematic process to collect and analyse experience gained from medical devices which have been placed on the market

3.14
risk
combination of the probability of occurrence of harm and the severity of that harm [SOURCE: ISO 14971:2007, definition 2.16]

3.15
risk management
systematic application of management policies, procedures, and practices to the tasks of analyzing, evaluating, controlling, and monitoring risk [SOURCE: ISO 14971:2007, definition 2.22]

3.16
sterile medical device
medical device intended to meet the requirements for sterility

NOTE to entry: The requirements for sterility of a medical device might be subject to applicable regulatory requirements or standards.

4 Quality management system

4.1 General requirements

4.1.1 The organization shall document a quality management system and maintain its effectiveness in accordance with the requirements of this International Standard and applicable regulatory requirements.

The organization shall establish, implement and maintain any requirement, procedure, activity or special arrangement required by this International Standard and applicable regulatory requirements.

The organization shall document the role(s) undertaken by the organization under the applicable regulatory requirements.

NOTE Roles undertaken by the organization might include manufacturer, authorized representative, importer, distributor, specification developer or designer of medical device.

4.1.2 The organization shall:

a) determine the processes needed for the quality management system and the application of these processes throughout the organization taking into account the roles undertaken by the organization,

b) apply a risk based approach to the appropriate processes needed for the quality management system, and

c) determine the sequence and interaction of these processes.

NOTE Processes needed for the quality management system referred to above include processes for management activities, provision of resources, product realization, and measurement, analysis, and improvement, including post market surveillance.

4.1.3 For each quality management system process, the organization shall:

a) determine criteria and methods needed to ensure that both the operation and control of these processes are effective;
b) ensure the availability of resources and information necessary to support the operation and monitoring of these processes;
c) implement actions necessary to achieve planned results and maintain the effectiveness of these processes;
d) monitor, measure as appropriate, and analyse these processes; and
e) establish and maintain records needed to demonstrate conformance to this International Standard and compliance with applicable regulatory requirements (see 4.2.4).

4.1.4 The organization shall manage these quality management system processes in accordance with the requirements of this International Standard and applicable regulatory requirements.

Changes to be made to these processes shall be:

a) evaluated for their impact on the quality management system

b) evaluated for their impact on the medical devices produced under this quality management system, and

c) controlled in accordance with the requirements of this International Standard and applicable regulatory requirements.

4.1.5 When an organization chooses to outsource any process that affects product conformity with requirements, the organization shall monitor and ensure control over such processes. The controls shall be proportional with the risk involved and the ability of the external party to meet the requirements and shall include written quality agreements.

NOTE 1 An "outsourced process" is a process that the organization needs for its quality management system and which the organization chooses to have performed by an external party.

NOTE 2 Outsourcing processes does not absolve the organization of the responsibility of conformity to this International Standard and to customer and applicable regulatory requirements. The type and extent of control to be applied to the outsourced processes can be influenced by factors such as:

a) The potential impact of the outsourced process on the organization's capability to provide product that conforms to requirements,

b) The extent to which the control for the process is shared, and

c) The capability of achieving the necessary control through the application of 7.4.

4.1.6 The organization shall document procedures for the validation of the application of computer software used in the quality management system. Such software applications shall be validated for their intended use prior to initial use and, as appropriate, after changes to such software or its application.

The specific approach and activities associated with software validation and re-validation shall be proportional with the risk associated with the use of the software.

Records of such activities shall be maintained (see 4.2.4)

4.2 Documentation requirements

4.2.1 General

4.2.1.1 The quality management system documentation (see 4.2.3) shall include:

a) documented statements of a quality policy and quality objectives,
b) a quality manual,
c) documented procedures and records required by this International Standard,
d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation, and control of its processes, and
e) any other documentation specified by applicable regulatory requirements.

NOTE 1 The documentation can be in any form or type of medium.

NOTE 2 The extent of the quality management system documentation can differ from one organization to another due to:

- the size of the organization and type of activities,
- the complexity of processes and their interactions,
- the competence of personnel, and
- the product and process risks.

4.2.1.2 For each medical device or medical device family, the organization shall establish and maintain a file(s) either containing or referencing documents generated to demonstrate compliance to the requirement of this International Standard and applicable regulations. The content of this(ese) file(s) shall include but is(are) not limited to:

a) general description of the medical device, intended use/purpose, and labeling including any instructions for use;
b) product, packaging, storage, and distribution specifications;
c) manufacturing procedures and specifications;
d) measuring and monitoring procedures;
e) traceability of changes made to the medical device during the lifetime of the medical device; and,
f) as appropriate, installation and servicing activities.

4.2.2 Quality manual

The organization shall document a quality manual that includes:

a) the scope of the quality management system, including details of and justification for any exclusion or non-application;
b) the documented procedures established for the quality management system, or reference to them; and
c) a description of the interaction between the processes of the quality management system.

The quality manual shall outline the structure of the documentation used in the quality management system.

4.2.3 Control of documents

Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.

A documented procedure shall be established to define the controls needed to:

a) review and approve documents for adequacy prior to issue,
b) review and update as necessary and re-approve documents,
c) ensure that changes and the current revision status of documents are identified,
d) ensure that relevant versions of applicable documents are available at points of use,
e) ensure that documents remain legible and readily identifiable,
f) ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled,
g) prevent deterioration or loss of documents, and
h) prevent the unintended use of obsolete documents and to apply suitable identification to them.

The organization shall ensure that changes to documents are reviewed and approved either by the original approving function or another designated function that has access to pertinent background information upon which to base its decisions.

The organization shall define the period for which at least one copy of obsolete documents shall be retained. This period shall ensure that documents to which medical devices have been manufactured and tested are available for at least the lifetime of the medical device as defined by the organization, but not less than the retention period of any resulting record (see 4.2.4), or as specified by applicable regulatory requirements.

4.2.4 Control of records

Records shall be maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system.

The organization shall document procedures to define the controls needed for the identification, storage, security and integrity, retrieval, retention time and disposition of records.

The organization shall define methods for protecting confidential health information contained in records taking into account the applicable regulatory requirements.

Records shall remain legible, readily identifiable and retrievable. Changes to a record shall remain identifiable.

The organization shall retain the records until at least the end of life of the medical device as defined by the organization, or as specified by applicable regulatory requirements, but not less than two years from the date of the creation of the record.

NOTE Records can be in any format or type of medium.

5 Management responsibility

5.1 Management commitment

Top management shall provide evidence of its commitment to the development and implementation of the quality management system and maintenance of its effectiveness by:

a) communicating to the organization the importance of meeting customer as well as applicable regulatory requirements,
b) establishing the quality policy,
c) ensuring that quality objectives are established,
d) conducting management reviews, and
e) ensuring the availability of resources.

5.2 Customer focus

Top management shall ensure that customer requirements and applicable regulatory requirements are determined and are met.

5.3 Quality policy

Top management shall ensure that the quality policy:

a) is applicable to the purpose of the organization,
b) includes a commitment to comply with requirements and to maintain the effectiveness of the quality management system,
c) provides a framework for establishing and reviewing quality objectives,
d) is communicated and understood within the organization, and
e) is reviewed for continuing suitability.

5.4 Planning

5.4.1 Quality objectives

Top management shall ensure that quality objectives, including those needed to meet applicable regulatory requirements and requirements for product, are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

5.4.2 Quality management system planning

Top management shall ensure that:

a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and
b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

NOTE Quality management system planning normally includes identification and implementation of action items that are intended to accomplish quality objectives, monitoring the progress toward completion of action items, and revision to the planning based on monitoring.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

Top management shall ensure that responsibilities and authorities are defined, documented, and communicated within the organization.

Top management shall establish the interrelation of all personnel who manage, perform and verify work affecting quality, and shall ensure the independence and authority necessary to perform these tasks.

NOTE Applicable regulatory requirements might prescribe the nomination of specific persons as responsible for activities related to monitoring experience from the post-production stage and reporting adverse events.

5.5.2 Management representative

Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes:

a) ensuring that processes needed for the quality management system are documented,
b) reporting to top management on the effectiveness of the quality management system and any need for improvement, and
c) ensuring the promotion of awareness of applicable regulatory requirements and quality management system requirements throughout the organization.

NOTE The responsibility of a management representative can include liaison with external parties, including regulatory authorities, on matters relating to the quality management system.

5.5.3 Internal communication

Top management shall ensure that, as appropriate, communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

5.6 Management review

5.6.1 General

Top management shall review the organization's quality management system at documented planned intervals to ensure its continuing suitability, adequacy, and effectiveness. The rationale for the interval shall be recorded (see 4.2.4). The review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. The requirements for the management review shall be documented.

Records from management reviews shall be maintained (see 4.2.4).

5.6.2 Review input

The input to management review shall include, but is not limited to, information arising from:

a) results of audits,
b) feedback as related to requirements in 8.2.1,
c) process performance and product conformity,
d) preventive and corrective actions,
e) follow-up actions from previous management reviews,
f) changes that could affect the quality management system,
g) recommendations for improvement, and
h) applicable new or revised regulatory requirements.

5.6.3 Review output

The output from management review shall be recorded (see 4.2.4) and include the input reviewed and any decisions and actions related to:

a) improvement needed to maintain the suitability, adequacy, and effectiveness of the quality management system and its processes;
b) improvement of product related to customer requirements;
c) changes needed to respond to applicable new or revised regulatory requirements; and
d) resource needs.

6 Resource management

6.1 Provision of resources

The organization shall determine and provide the resources needed to:

a) implement the quality management system and to maintain its effectiveness, and

b) meet applicable regulatory and customer requirements.

6.2 Human resources

6.2.1 General

Personnel performing work affecting product safety or performance shall be competent on the basis of appropriate education, training, skills and experience.

6.2.2 Competence, training, and awareness

The organization shall document the process(es) for establishing competence, providing needed training, and ensuring awareness of personnel.

The organization shall:

a) determine the necessary competence for personnel performing work affecting product safety or performance,
b) provide training or take other actions to achieve or maintain the necessary competence,
c) evaluate the effectiveness of the actions taken,
d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and
e) maintain appropriate records of education, training, skills and experience (see 4.2.4).

NOTE The methodology used to check effectiveness is proportional with the risk associated with the work for which the training or other action is being provided.

6.3 Infrastructure

6.3.1 The organization shall document the infrastructure needed to provide the controlled work environment, to achieve conformity to product requirements, prevent product mix-up and ensure orderly handling of product. Infrastructure includes, as appropriate:

a) buildings, workspace and associated utilities,
b) process equipment (both hardware and software), and
c) supporting services (such as transport, communication, or information systems).

6.3.2 The organization shall document requirements for the maintenance activities, including the interval of performing the maintenance activities, when such maintenance activities, or lack thereof, can affect product safety or performance. As appropriate, the documentation requirements shall apply to equipment used:

a) in production,
b) for the control of the work environment, and
c) in testing.

Records of such maintenance shall be maintained (see 4.2.4).

6.4 Work environment

6.4.1 General

6.4.1.1 The organization shall document the work environment needed to achieve conformity to product requirements.

6.4.1.2 If the work environment can have an adverse effect on product safety or performance, the organization shall document:

a) requirements for the work environment, and
b) procedures to monitor and control these work environment conditions.

NOTE 1 Work environment includes, but is not limited to, areas of infrastructure for production, inspection, storage and distribution. The term work environment relates to those conditions under which work is performed including physical, environmental and other factors (such as noise, temperature, humidity, lighting or weather).

NOTE 2 For additional information related to cleanrooms and associated controlled environments see for example ISO 14644 series.

6.4.1.3 The organization shall:

a) document requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could affect product safety or performance, and
b) ensure that all personnel who are required to work temporarily under special environmental conditions within the work environment are appropriately trained or supervised by a trained person.

6.4.1.4 As appropriate, special arrangements shall be documented for the control of contaminated or potentially contaminated product in order to prevent contamination of the work environment, personnel, or product.

NOTE Examples of special arrangements can include controlled and secured access, appropriate sanitation and utilities, appropriate physical separation of areas.

6.4.2 Particular requirements for sterile medical devices

In addition to 6.4.1, the organization shall establish the requirements for the work environment, taking into account the nature of the manufacturing process, in order to:

a) prevent contamination with particulate matter or microorganisms, and
b) maintain the degree of cleanliness during assembly or packaging operations.

7 Product realization

7.1 Planning of product realization

The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system.

The organization shall document a process(es) for risk management throughout product realization. Records of risk management activities shall be maintained (see 4.2.4).

In planning product realization, the organization shall determine the following, as appropriate:

a) quality objectives and requirements for the product;
b) the need to establish processes, documents (see 4.2.3), and provide resources specific to the product, including infrastructure and work environment;
c) required verification, validation and revalidation, monitoring, measurement, inspection and test activities, handling, storage, traceability specific to the product and the criteria for product acceptance; and
d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).

The output of this planning shall be in a form suitable for the organization's method of operations.

NOTE 1 A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan.

NOTE 2 The organization may also apply the requirements given in 7.3 to the development of product realization processes.

NOTE 3 For information related to risk management see other documents, for example ISO 14971.

NOTE 4 For information related to software life cycle processes see other documents, for example IEC/ISO 62304.

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

The organization shall determine:

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,
b) requirements not stated by the customer but necessary for specified or intended use, as known,
c) applicable regulatory requirements related to the product,
d) any user training needed to ensure specified performance and safe use of the product, and
e) any additional requirements determined by the organization.

NOTE Post-delivery activities include, for example, actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

7.2.2 Review of requirements related to the product

The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that:

a) product requirements are defined and documented,
b) contract or order requirements differing from those previously expressed are resolved,
c) applicable regulatory requirements are met,
d) any user training identified per requirements of 7.2.1 is available, and
e) the organization has the ability to meet the defined requirements.

Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).

When the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.

When product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

7.2.3 Communication

7.2.3.1 Customer communication

The organization shall document arrangements for communicating with customers in relation to:

a) product information,
b) enquiries, contracts or order handling, including amendments,
c) customer feedback, including complaints, and
d) advisory notices.

7.2.3.2 Communication with regulatory authorities

As appropriate, the organization shall communicate with regulatory authorities in accordance with planned arrangements.

7.3 Design and development

7.3.1 General

The organization shall document procedures for design and development.

7.3.2 Design and development planning

The organization shall plan and control the design and development of product. Planning documents shall be maintained and updated as appropriate, as the design and development progresses.

During design and development planning, the organization shall document:

a) the design and development stages,
b) the review(s) and decisions needed at each design and development stage,
c) the verification, validation, and design transfer activities that are appropriate at each design and development stage,
d) the responsibilities and authorities for design and development,
e) the methods to ensure traceability of design and development outputs to design and development inputs, and
f) the resources needed including necessary competence of personnel.

NOTE Design and development review, verification and validation have distinct purposes. They can be conducted and recorded separately or in any combination, as suitable for the product and the organization.

7.3.3 Design and development inputs

Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include:

a) functional, performance, usability and safety requirements, according to the intended use,
b) applicable regulatory requirements and standards,
c) applicable output(s) of risk management,
d) as appropriate, information derived from previous similar designs, and
e) other requirements essential for design and development.

These inputs shall be reviewed for adequacy and approved.

Requirements shall be complete, unambiguous, able to be verified or validated, and not in conflict with each other.

NOTE For information related to usability see other documents, for example ISO/IEC 62366.

7.3.4 Design and development outputs

The outputs of design and development shall be in a form suitable for verification against the design and development input and shall be approved prior to release.

Design and development outputs shall:

a) meet the input requirements for design and development,
b) provide appropriate information for purchasing, production and service provision,
c) contain or reference product acceptance criteria, and
d) specify the characteristics of the product that are essential for its safe and proper use.

Records of the design and development outputs shall be maintained (see 4.2.4).

NOTE 1 Information for production and service provision can include details for the preservation of product.

NOTE 2 Records of design and development outputs can include, but are not limited to specifications, manufacturing procedures, engineering drawings, source code, and engineering or research logbooks.

7.3.5 Design and development review

At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements to:

a) evaluate the ability of the results of design and development to meet requirements, and
b) identify and propose necessary actions.

Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed, as well as other specialist personnel.

Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4).

NOTE Applicable regulatory requirements might require participation in the design review by a person independent of the design stage under review.

7.3.6 Design and development verification

Design and development verification shall be performed in accordance with planned arrangements to ensure that the design and development outputs have met the design and development input requirements.

The organization shall document verification plans that include, as appropriate, methods, acceptance criteria, and sample size(s).

If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), verification shall include confirmation that the design outputs meet design inputs when connected or interfaced.

Records of the results and conclusions of the verification including, as appropriate, rationale for sample size and necessary actions shall be maintained (see 4.2.3 and 4.2.4).

NOTE Applicable regulatory requirements might have additional verification requirements.

7.3.7 Design and development validation

Design and development validation shall be performed in accordance with planned arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use. Validation shall be completed prior to formal transfer of the product to the customer.

The organization shall document validation plans that include, as appropriate, methods, acceptance criteria, and sample size(s).

Design validation shall be conducted on representative product. The rationale for the choice of product used for validation shall be recorded (see 4.2.4).

As part of design and development validation, the organization shall perform clinical evaluations or performance evaluations of the medical device in accordance with applicable regulatory requirements.

If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), validation shall include confirmation that the requirements for the specified application or intended use have been met when so connected or interfaced.

Records of the results and conclusion of validation including, as appropriate, rationale for sample size any necessary actions shall be maintained (see 4.2.3 and 4.2.4).

NOTE 1 For some medical devices, validation can only be performed following assembly and installation at point of use.

NOTE 2 Provision of the medical device for purposes of clinical evaluations or performance evaluation is not considered to be formal transfer to the customer.

NOTE 3 Representative product includes initial production units, lots, or batches or their equivalents.

7.3.8 Design and Development Transfer

The organization shall document transfer plans by considering the following, as appropriate, and not limited to:

a) product specifications,
b) process specifications and process validation(s),
c) work environment,
d) supplier ability to fulfill agreed requirements,
e) personnel competence,
f) installation, and

g) service.

Design and development transfer shall be performed in accordance with planned arrangements and documented procedures to ensure that design and development outputs are verified as suitable for manufacturing before becoming final production specifications and that production capability can meet product requirements.

Results and conclusions of the transfer shall be recorded (see 4.2.4).

7.3.9 Control of design and development changes

7.3.9.1 The organization shall establish processes to control design and development changes that affect the design of the medical device and determine the significance of the change to product function, performance, safety, and applicable regulatory requirements for the intended use and take appropriate action.

7.3.9.2 Design and development changes shall be identified and records maintained. Before implementation, the changes shall be:

a) reviewed,
b) verified,
c) validated, as appropriate, and
d) approved.

7.3.9.3 The review of design and development changes shall include evaluation of the effect of the changes on:

a) constituent parts and product in process or already delivered,
b) outputs of risk management, and
c) product realization processes.

7.3.9.4 Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).

7.3.10 Design and development records

The organization shall maintain a design and development file for each medical device or medical device family including or referencing records generated to demonstrate compliance to the requirements for design and development, including design and development changes.

7.4 Purchasing

7.4.1 Purchasing process

7.4.1.1 General

The organization shall document procedures (see 4.2.3) to ensure that purchased product conforms to specified purchasing information.

7.4.1.2 Supplier approval

The organization shall plan the supplier selection, and shall establish selection and evaluation criteria, evaluate and approve suppliers based on their ability to meet defined criteria and supply product in accordance with the organization's requirements and applicable regulatory requirements. The established criteria for selection and evaluation shall be:

a) based on the capability or performance of the supplier,
b) based on the effect of the purchased product on the safety and performance of the medical device
c) proportional to the risk associated with the medical device.

7.4.1.3 Monitoring of suppliers

The organization shall plan the supplier monitoring and re-evaluation criteria. A supplier's performance in meeting requirements for the purchased product shall be monitored and the results of the monitoring shall provide an input into the supplier re-evaluation process.

Non fulfilment of purchasing specifications and expectations shall be handled with the supplier proportional to the risk associated with the purchased product and compliance with applicable regulatory requirements.

7.4.1.4 Supplier records

Records of the results of evaluation and monitoring, re-evaluation of supplier performance, and any necessary actions arising from these shall be maintained (see 4.2.4).

7.4.2 Purchasing information

Purchasing information shall describe or reference the product to be purchased, including as appropriate:

a) product specifications;
b) requirements for product acceptance, procedures, processes and equipment;
c) requirements for qualification of personnel; and
d) quality management system requirements.

The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

Purchasing information shall include, as applicable, a written agreement that the suppliers notify the organization of changes in the purchased product prior to implementation of any changes that affect the ability of the purchased product to meet specified purchase requirements.

To the extent required for traceability given in 7.5.3.2, the organization shall maintain relevant purchasing information, i.e. documents (see 4.2.3) and records (see 4.2.4).

7.4.3 Verification of purchased product

The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchasing requirements. The extent of verification activities shall be based on the result of the evaluation and re-evaluation of the supplier and proportional to the risks associated with the purchased product.

When the organization becomes aware of any changes to the purchased product, the organization shall determine whether these changes affect the product realization process or the medical device.

When the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.

Records of the verification shall be maintained (see 4.2.4).

7.5 Production and service provision

7.5.1 Control of production and service provision

7.5.1.1 General requirements

Production and service provision shall be planned, carried out, monitored and controlled to ensure that medical devices conform to specification. Production controls shall include, but are not limited to, as appropriate:

a) the documentation of procedures and methods relevant for the control of production (see 4.2.3),
b) equipment qualification,
c) the implementation of monitoring and measurement of process parameters and product characteristics,
d) the availability and use of monitoring and measuring equipment,
e) the implementation of defined operations for labelling and packaging, and
f) the implementation of product release, delivery and post-delivery activities

The organization shall establish and maintain a record (see 4.2.4) for each batch of medical devices that provides traceability to the extent specified in 7.5.3 and identifies the amount manufactured and amount approved for distribution. The record shall be verified and approved.

NOTE A batch can be a single medical device.

7.5.1.2 Control of production and service provision — Specific requirements

7.5.1.2.1 Cleanliness of product and contamination control

The organization shall document requirements for cleanliness or contamination control of product if:

a) product is cleaned by the organization prior to sterilization or its use;
b) product cannot be cleaned prior to sterilization or its use, and its cleanliness is of significance in use;
c) product is supplied non-sterile to be subjected to a cleaning process prior to sterilization or its use;
d) product is supplied to be used non-sterile, and its cleanliness is of significance in use; or
e) process agents are to be removed from product during manufacture.

If product is cleaned in accordance with a) or c) above, the requirements contained in 6.4.1.2 a) and 6.4.1.2 b) do not apply prior to the cleaning process.

7.5.1.2.2 Installation activities

The organization shall document requirements for installation and acceptance criteria for installation verification, as appropriate.

If the agreed customer requirements allow installation to be performed by an external party other than the organization or its supplier, the organization shall provide documented requirements for installation and verification.

Records of installation and verification performed by the organization or its supplier shall be maintained (see 4.2.4).

7.5.1.2.3 Servicing activities

If servicing is a requirement, the organization shall document procedures, reference materials, and reference measurement procedures, as necessary, for performing servicing activities and verifying that they meet the requirements.

The organization shall analyse records of servicing activities carried out by the organization or supplier to determine if the information shall be handled as a complaint(s).

The organization shall consider records of servicing activities as a source of information to be analysed as appropriate for the improvement process.

Records of servicing activities carried out by the organization or its supplier shall be maintained (see 4.2.4).

NOTE Servicing can include, for example, repair and maintenance.

7.5.1.3 Particular requirements for sterile medical devices

The organization shall maintain records of the process parameters for the sterilization process that were used for each sterilization batch (see 4.2.4). Sterilization records shall be traceable to each production batch of medical devices.

7.5.2 Validation of processes for production and service provision

7.5.2.1 General requirements

The organization shall validate any processes for production and service provision where the resulting output cannot be or is not verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.

Validation shall demonstrate the ability of these processes to achieve planned results consistently.

The organization shall document validation plans that include, as appropriate, methods, acceptance criteria, and sample size(s).

The organization shall document procedures for processes to be validated including, as appropriate:

a) defined criteria for review and approval of the processes,

b) equipment qualification and qualification of personnel,
c) use of specific methods and procedures,
d) requirements for records (see 4.2.4),
e) revalidation, including conditions triggering revalidation, and
f) approval of changes to the processes.

The organization shall document procedures for the validation of the application of computer software (and changes to such software or its application) for production and service provision that affect the ability of the product to conform to specifications. Such software shall be validated prior to use.

Records of the results, conclusion and any necessary actions from the validation shall be maintained (see 4.2.4).

7.5.2.2 Particular requirements for sterile medical devices

The organization shall document procedures (see 4.2.3) for the validation of sterilization and packaging processes for sterile barrier systems.

Packaging processes for sterile barrier systems and sterilization processes shall be validated prior to implementation and following product or process changes, as appropriate. Records of the results, conclusion and any necessary actions from the validation shall be maintained (see 4.2.4)

NOTE For additional information related to packaging validation see, for example, ISO 11607-1, ISO 11607-2 and ISO TS 16775.

7.5.3 Identification and traceability

7.5.3.1 Identification

As appropriate, the organization shall identify the product by suitable means throughout product realization, and shall document procedures for such product identification.

If required by applicable regulatory requirements, the organization shall document a system to assign unique device identification to the medical device.

The organization shall document procedures to ensure that medical devices returned to the organization are identified and distinguished from conforming product.

7.5.3.2 Traceability

7.5.3.2.1 General

The organization shall document procedures and maintain records for traceability (see 4.2.4). These procedures shall define the extent of traceability in accordance with applicable regulatory requirements. Traceability shall enable the organization to investigate problems, including customer complaints, and to implement corrections or corrective actions.

The records shall identify where the medical device has been delivered by the organization (see 4.2.4).

NOTE The extent of traceability can be in two directions, forward to customers and backward to raw materials, components and processes used in manufacturing.

7.5.3.2.2 Particular requirements for implantable medical devices

In defining the records required for traceability, the organization shall include records of all components, materials and work environment conditions, if these could cause the medical device not to satisfy its specified safety and performance requirements.

The organization shall require that its suppliers or distributors maintain records of the distribution of medical devices to allow traceability and that such records are available for inspection. Records of the name and address of the shipping package consignee shall be maintained (see 4.2.4).

7.5.3.3 Status identification

The organization shall identify the product status with respect to monitoring and measurement requirements throughout product realization. Identification of product status shall be maintained throughout production, storage, installation and servicing of the product to ensure that only product that has passed the required inspections and tests (or released under an authorized concession) is dispatched, used or installed.

7.5.4 Customer property

The organization shall identify, verify, protect, and safeguard customer property provided for use or incorporation into the product while it is under the organization's control or being used by the organization. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer and maintain records (see 4.2.4).

NOTE Customer property can include intellectual property or confidential health information.

7.5.5 Preservation of product

7.5.5.1 The organization shall document procedures for preserving the conformity of product to requirements during internal processing, storage, handling, and distribution. Preservation shall apply to the constituent parts of a medical device.

NOTE Sterile barrier systems of sterile medical devices are a constituent part of a medical device.

7.5.5.2 The organization shall protect the medical device from alteration, contamination or damage when exposed to expected conditions and hazards during processing, storage, handling, and distribution by:

a) Designing and constructing suitable packaging and shipping containers, or
b) Documenting requirements for special conditions needed if packaging alone cannot provide the preservation.

In case special conditions have to be followed, they shall be controlled and recorded (see 4.2.4).

NOTE Examples can include products which require temperature control during transport and storage or products requiring special conditions for processing, storage, handling, and distribution.

7.6 Control of monitoring and measuring equipment

The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements as per documented procedures.

As necessary to ensure valid results, measuring equipment shall:

a) be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards. When no such standards exist, the basis used for calibration or verification shall be recorded (see 4.24);
b) be adjusted or re-adjusted as necessary;
c) have identification in order to determine its calibration status;
d) be safeguarded from adjustments that would invalidate the measurement result; and
e) be protected from damage and deterioration during handling, maintenance and storage.

The organization shall perform calibration or verification in accordance with planned arrangements and documented procedures.

In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected.

Records of the results of calibration and verification shall be maintained (see 4.2.4).

When used in the monitoring and measurement of requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to use and reconfirmed as necessary.

NOTE For guidance related to measurement management systems see other documents, for example ISO 10012.

8 Measurement, analysis and improvement

8.1 General

The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed to:

a) demonstrate conformity of the product,
b) ensure conformity of the quality management system, and
c) maintain the effectiveness of the quality management system.

This shall include determination of appropriate methods, including statistical techniques, and the extent of their use.

NOTE Applicable regulatory requirements might require documented procedures for implementation and control of the application of statistical techniques.

8.2 Monitoring and measurement

8.2.1 Feedback

8.2.1.1 General

As one of the measurements of the effectiveness of the quality management system, the organization shall gather and monitor information relating to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined and documented.

The organization shall document procedures for the feedback process. This feedback process shall include provisions to gather data from production as well as post-production activities.

The information gathered in the feedback process shall serve as input into risk management for monitoring and maintaining the product requirements as well as potential input into the product realization processes.

If applicable regulatory requirements require the organization to gain specific experience from the post-production phase, the review of this experience shall form part of the feedback process.

8.2.1.2 Complaint handling and reporting to regulatory authorities

8.2.1.2.1 Complaint handling

The organization shall document procedures for timely complaint handling in accordance with applicable regulatory requirements.

These procedures shall include at a minimum requirements and responsibilities for:

a) Receiving information,
b) Evaluating information to determine if the feedback constitutes a complaint,
c) Investigating complaints,
d) Determining the need to report the information to the appropriate regulatory authorities,
e) Handling of complaint-related product,
f) Determining and initiating corrections or corrective actions, and
g) Defining requirements for complaint records.

If any complaint is not investigated, justification shall be documented. Any correction or corrective action resulting from the complaint handling process shall be documented.

If an investigation determines activities outside the organization contributed to the complaint, relevant information shall be exchanged between the organization and the external party involved.

Complaint handling records shall be maintained (see 4.2.4).

8.2.1.2.2 Reporting to regulatory authorities

If applicable regulatory requirements require notification of complaints that meet specified reporting criteria of adverse events the organization shall document procedures for providing notification to the appropriate regulatory authorities.

Records of reporting to regulatory authorities shall be maintained (see 4.2.4).

8.2.2 Internal audit

The organization shall conduct internal audits at planned intervals to determine whether the quality management system:

a) conforms to the planned arrangements, to the requirements of this International Standard, to the quality management system requirements established by the organization, and applicable regulatory requirements; and

b) is effectively implemented and maintained.

The organization shall document a procedure to describe the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.

An audit program shall be planned, taking into consideration the status and importance of the processes and area(s) to be audited, as well as the results of previous audits. If changes are made to the planned audit program, the justification for the change shall be recorded (see 4.2.4). The audit criteria, scope, interval and methods shall be defined and recorded (see 4.2.4). The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

Records of the audits and their results, including identification of the processes and areas reviewed and the conclusions, shall be maintained (see 4.2.4).

The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results.

NOTE For guidance related to auditing see other documents, for example ISO 19011.

8.2.3 Monitoring and measurement of processes

The organization shall apply suitable methods for monitoring and, as appropriate, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate.

NOTE When determining suitable methods, it is advisable that the organization consider the type and extent of monitoring or measurement appropriate to each of its processes in relation to their impact on the conformity to product requirements and on the effectiveness of the quality management system.

8.2.4 Monitoring and measurement of product

8.2.4.1 General requirements

The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at applicable stages of the product realization process in accordance with the planned arrangements and documented procedures.

Evidence of conformity with the acceptance criteria shall be maintained.

As appropriate, records shall identify the test equipment used to perform measurement activities. The identity of the person(s) authorizing release of product shall be recorded (see 4.2.4).

Product release and service delivery shall not proceed until the planned arrangements have been satisfactorily completed.

8.2.4.2 Particular requirement for implantable medical devices

The organization shall record the identity of personnel performing any inspection or testing.

8.3 Control of nonconforming product

8.3.1 General

The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The organization shall document a procedure to define the controls and related responsibilities and authorities for the identification, documentation, segregation, evaluation, and disposition of nonconforming product.

The evaluation of nonconformity shall include a determination of the need for an investigation and notification of any external party responsible for the nonconformity.

Nonconforming product shall be considered for corrective action.

Records of the nature of the nonconformities and any subsequent action(s) taken, including the evaluation, any investigation and the rationale for decisions shall be maintained (see 4.2.4)

8.3.2 Actions in response to nonconforming product before delivery

As appropriate, the organization shall deal with nonconforming product by one or more of the following ways by:

a) taking action to eliminate the detected nonconformity;
b) authorizing its use, release or acceptance under concession;
c) taking action to preclude its original intended use or application.

The organization shall ensure that nonconforming product is accepted by concession only if the justification is provided, approval(s) are obtained, and applicable regulatory requirements are met. Records of the acceptance by concession and the identity of the person(s) authorizing the concession shall be maintained (see 4.2.4).

8.3.3 Actions in response to nonconforming product after delivery

8.3.3.1 When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity. Records of actions taken shall be maintained (see 4.2.4).

8.3.3.2 The organization shall document procedures for the issuance and implementation of advisory notices. These procedures shall be capable of being implemented at any time. Records of actions relating to the issuance and implementation of advisory notices shall be maintained (see 4.2.4).

8.3.4 Rework

The organization shall perform rework in accordance with documented procedures or work instruction that takes into account the potential adverse effect(s) of the rework on the product. These shall undergo the same review and approval as the original procedure or work instruction.

As applicable, after the completion of rework the product shall be retested to ensure that the product meets requirements and applicable regulatory requirements.
Records of rework shall be maintained (see 4.2.4)

8.4 Analysis of data

The organization shall document procedures to determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate if improvement of the effectiveness of the quality management system can be made. The procedures shall include determination of appropriate methods including statistical techniques and the extent of their use.

The analysis of data shall include data generated as a result of monitoring and measurement and from other relevant sources and include, as a minimum, input from:

a) feedback,
b) conformity to product requirements,
c) characteristics and trends of processes and products including opportunities for improvement,
d) suppliers,
e) audits, and
f) service reports, as appropriate.

Records of the results of analyses shall be maintained (see 4.2.4).

8.5 Improvement

8.5.1 General

The organization shall identify and implement any changes necessary to ensure and maintain the continued suitability and effectiveness of the quality management system as well as product safety and performance through the use of the quality policy, quality objectives, audit results, post market surveillance, analysis of data, corrective and preventive actions and management review.

8.5.2 Corrective action

The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. .

Corrective actions shall be appropriate to the effects of the nonconformities encountered.

The organization shall document a procedure to define requirements for:

a) reviewing nonconformities (including complaints);
b) determining the causes of nonconformities;
c) evaluating the need for action to ensure that nonconformities do not recur;
d) planning and documenting action needed and implementing such action in a timely manner, including, as appropriate, updating documentation;
e) verifying that the corrective action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device; and
f) reviewing the effectiveness of corrective action taken.

Records of the results of any investigation and *action taken* shall be maintained (see 4.2.4)

8.5.3 Preventive action

The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence.

Preventive actions shall be appropriate to the effects of the potential problems.

The organization shall document a procedure to describe requirements for:

a) determining potential nonconformities and their causes,
b) evaluating the need for action to prevent occurrence of nonconformities,
c) planning and documenting action needed, and implementing such action in a timely manner, including, as appropriate, updating documentation,
d) verifying that the action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of products, and
e) reviewing the effectiveness of the preventive action taken, as appropriate.

Records of the results of any investigations and of action taken shall be maintained (see 4.2.4).

Annex A (informative) Comparison of content between ISO 13485:2003 and ISO DIS2 13485:2015

This annex documents the similarities and differences between requirements clauses and subclauses and key informative clauses and subclauses of this International Standard and the earlier version, ISO 13485:2003..

ISO 13485:2003	ISO 13485:201x
0 Introduction **0.1 General** This International Standard specifies requirements for a quality management system that can be used by an organization for the design and development, production, installation and servicing of medical devices, and the design, development, and provision of related services. It can also be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer and regulatory requirements. Information marked "NOTE" is for guidance in understanding or clarifying the associated requirement. It is emphasized that the quality management system requirements specified in this International Standard are complementary to technical requirements for products. The adoption of a quality management system should be a strategic decision of an organization. The design and implementation of an organization's quality management system is influenced by varying needs, particular objectives, the products provided, the processes employed and the size and structure of the organization. It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation. There is a wide variety of medical devices and some of the particular requirements of	**0 Introduction** **0.1 General** This International Standard specifies requirements for a quality management system that can be used by an organization involved in one or more stage(s) of the life-cycle of a medical device including the design and development, production, storage and distribution, installation or servicing of medical devices, and the design, development, or provision of associated activities (e.g. technical support). The requirements in this standard may also be used by suppliers or other external parties providing product (e.g., sterilization services, calibration services, distribution services) to such organizations. Such a supplier or external party may voluntarily choose to conform to the requirements of this standard or may be required by contract to conform. Several jurisdictions have regulatory requirements for the application of quality management systems by organizations with a variety of roles in the supply chain for medical devices. Consequently, this standard expects that the organization: • identifies its role(s) under applicable regulatory requirements, • identifies the regulatory requirements that are applicable for its activities under these roles, and • incorporates these applicable regulatory requirements within its quality management system. This International Standard can also be used by internal and external parties,

ISO 13485:2003	ISO 13485:201x
this International Standard only apply to named groups of medical devices. These groups are defined in Clause 3.	including certification bodies, to assess the organization's ability to meet customer and regulatory requirements applicable to the quality management system and the organization's own requirements. It is emphasized that the quality management system requirements specified in this International Standard are complementary to the technical requirements for products that are necessary to meet customer and applicable regulatory requirements for safety and performance. The adoption of a quality management system is a strategic decision of an organization. The design and implementation of an organization's quality management system is influenced by: a) its organizational environment, changes in that environment, and the risks associated with that environment; b) its varying needs; c) its particular objectives; d) the products it provides; e) the processes it employs; f) its size and organizational structure; and g) applicable regulatory requirements. It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation. There is a wide variety of medical devices and some of the particular requirements of this International Standard only apply to named groups of medical devices. These groups are defined in Clause 3.
0.2 Process approach This International Standard is based on a process approach to quality management. Any activity that receives inputs and converts them to outputs can be considered as a process. For an organization to function effectively, it has to identify and manage numerous linked processes.	**0.2 Process approach** This International Standard is based on a process approach to quality management. Any activity that receives input(s) and converts them to output(s) can be considered as a process. Often the output from one process directly forms the input to the next process. For an organization to function effectively, it has to identify and manage numerous

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Often the output from one process directly forms the input to the next. The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management, can be referred to as the "process approach".	linked processes. The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management to produce the desired outcome, can be referred to as the "process approach." When used within a quality management system, such an approach emphasizes the importance of: a) understanding and meeting requirements, b) considering processes in terms of added value, c) obtaining results of process performance and effectiveness, and d) improving processes based on objective measurement.
0.3 Relationship with other standards **0.3.1 Relationship with ISO 9001** While this is a stand-alone standard, it is based on ISO 9001. Those clauses or subclauses that are quoted directly and unchanged from ISO 9001 are in normal font. The fact that these subclauses are presented unchanged is noted in Annex B. Where the text of this International Standard is not identical to the text of ISO 9001, the sentence or indent containing that text as a whole is shown in italics (in blue italics for electronic versions). The nature and reasons for the text changes are noted in Annex B. **0.3.2 Relationship with ISO/TR 14969** ISO/TR 14969 is a Technical Report intended to provide guidance for the application of ISO 13485.	**0.3 Relationship with ISO 9001** While this is a stand-alone standard, it is based on, and follows the format of, ISO 9001:2008 for the convenience of users in the medical device sector.

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0.4 Compatibility with other management systems This International Standard follows the format of ISO 9001 for the convenience of users in the medical devicecommunity. This International Standard does not include requirements specific to other management systems, such as those particular to environmental management, occupational health and safety management, or financial management. However, this International Standard enables an organization to align or integrate its own quality management system with related management system requirements. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that complies with the requirements of this International Standard.	**0.4 Compatibility with other management systems** This International Standard does not include requirements specific to other management systems, such as those particular to environmental management, occupational health and safety management, or financial management. However, this International Standard enables an organization to align or integrate its own quality management system with related management system requirements. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that complies with the requirements of this International Standard.
Quality management systems — Requirements **1 Scope** **1.1 General** This International Standard specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services. The primary objective of this International Standard is to facilitate harmonized medical device regulatory requirements for quality management systems. As a result, it includes some particular requirements for medical devices and excludes some of the requirements of ISO 9001 that are not appropriate as regulatory requirements. Because of these exclusions, organizations whose quality management systems conform to this International Standard cannot claim conformity to ISO 9001 unless their quality management systems conform to all the requirements of ISO 9001 (see Annex B)	**Quality management systems — Requirements** **1 Scope** **1.1 General** This International Standard specifies requirements for a quality management system that can be used by an organization involved in one or more stages of the life-cycle including the design and development, production, storage and distribution, installation, or servicing of a medical device and the design, development or provision of associated activities (e.g. technical support). The quality management system of the organization demonstrates the ability to consistently meet customer and applicable regulatory requirements. It may also be used by suppliers or external parties that provide goods and quality management system related services to such organizations. The main objective of this International Standard is to facilitate global alignment of appropriate regulatory requirements for quality management systems applicable to organizations providing medical devices. As a result, it includes some particular requirements for medical devices and excludes some of the requirements of ISO

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	9001:2008 that are not appropriate as regulatory requirements. Because of these exclusions, organizations whose quality management systems conform to this International Standard cannot claim conformity to ISO 9001:2008 unless their quality management system conforms to all the requirements of ISO 9001:2008.
1.2 Application All requirements of this International Standard are specific to organizations providing medical devices, regardless of the type or size of the organization. If regulatory requirements permit exclusions of design and development controls (see 7.3), this can be used as a justification for their exclusion from the quality management system. These regulations can provide alternative arrangements that are to be addressed in the quality management system. It is the responsibility of the organization to ensure that claims of conformity with this International Standard reflect exclusion of design and development controls [see 4.2.2 a) and 7.3]. If any requirement(s) in Clause 7 of this International Standard is(are) not applicable due to the nature of the medical device(s) for which the quality management system is applied, the organization does not need to include such a requirement(s) in its quality management system [see 4.2.2 a)]. The processes required by this International Standard, which are applicable to the medical device(s), but which are not performed by the organization, are the responsibility of the organization and are accounted for in the organization's quality management system [see 4.1 a)]. In this International Standard the terms "if appropriate" and "where appropriate" are used several times. When a requirement is qualified by either of these phrases, it is deemed to be "appropriate" unless the organization can document a justification otherwise. A requirement is considered "appropriate" if it is necessary in order for • the product to meet specified requirements, and/or • the organization to carry out corrective action.	**1.2 Application** All requirements of this International Standard are specific to organizations regardless of their type or size. Wherever requirements are specified as applying to medical devices, the requirements apply equally to associated services as supplied by the organization. The processes required by this International Standard, which are applicable to the medical device(s), but which are not performed by the organization, are the responsibility of the organization and are accounted for in the organization's quality management system by monitoring, maintaining, and controlling the processes. If applicable regulatory requirements permit exclusions of design and development controls, this can be used as a justification for their exclusion from the quality management system. These regulatory requirements can provide alternative arrangements that are to be addressed in the quality management system. It is the responsibility of the organization to ensure that claims of conformity with this International Standard reflect exclusion of design and development controls. If any requirement(s) in Clauses 6, 7 or 8 of this International Standard is (are) not applicable due to the activities undertaken by the organization or the nature of the medical device(s) for which the quality management system is applied, the organization does not need to include such a requirement(s) in its quality management system. For the clauses that are determined to be not applicable, the organization documents justification as described section 4.2.2. In this International standard the following terms or phases are used in the context described below:

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	• When a requirement is qualified by the phrase 'as appropriate', it is deemed to be 'appropriate' unless the organization can justify otherwise. A requirement is considered 'appropriate' if it is necessary for: o the product to meet requirements; o the organization to carry out corrective action; or o the organization to manage risks. • When a requirement is required to be 'documented', it is also required to be established, implemented and maintained. • When the term 'risk' is used, the application of the term is within the scope of this International standard and pertains to: o the safety or performance requirements or o meeting applicable regulatory requirements. • When the term 'product' is used, it can also mean 'service'. Product applies to outputs that are intended for, or required by, a customer, or any intended output resulting from a product realization process. • When the term 'regulatory requirements' is used, it encompasses statutory, regulatory and legal requirements. The application of the term 'regulatory requirements' is limited to requirements for the quality management system and the safety or performance of the medical device. • Information marked "NOTE" is for guidance in understanding or clarifying the associated requirement.
2 Normative references The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies. ISO 9000:2000, Quality management systems — Fundamentals and vocabulary	**2 Normative references** The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies. ISO 9000:2005, Quality management systems — Fundamentals and vocabulary

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3 Terms and definitions For the purposes of this document, the terms and definitions given in ISO 9000 apply, together with the following. The following terms, used in this edition of ISO 13485 to describe the supply chain, have been changed to reflect the vocabulary currently used: **supplier ----------> organization ----------> customer** The term "organization" replaces the term "supplier" used in ISO 13485:1996, and refers to the unit to which this International Standard applies. Also, the term "supplier" now replaces the term "subcontractor". Throughout the text of this International Standard, wherever the term "product" occurs, it can also mean"service". Wherever requirements are specified as applying to "medical devices", the requirements apply equally to related services as supplied by the organization. The following definitions should be regarded as generic, as definitions provided in national regulations can differ slightly and take precedence.	**3 Terms and definitions** For the purposes of this document, the terms and definitions given in ISO 9000 together with the following apply. The following definitions should be regarded as generic, as definitions provided in applicable regulatory requirements can differ slightly and take precedence.
3.1 **active implantable medical device** active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure	
3.2 **active medical device** medical device relying for its functioning on a source of electrical energy or any	

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source of power other than that directly generated by the human body or gravity	
3.3 **advisory notice** notice issued by the organization, subsequent to delivery of the medical device, to provide supplementary information and/or to advise what action should be taken in • the use of a medical device, • the modification of a medical device, • the return of the medical device to the organization that supplied it, or • the destruction of a medical device **NOTE** Issue of an advisory notice might be required to comply with national or regional regulations.	**3.1** **advisory notice** notice issued by the organization, subsequent to delivery of the medical device, to provide supplementary information or to advise what action should be taken in the: • use of a medical device, • modification of a medical device, • return of the medical device to the organization that supplied it, or • destruction of a medical device NOTE to entry: Issuance of an advisory notice might be required to comply with applicable regulatory requirements.
	3.2 **authorized representative** any natural or legal person who has received a documented mandate from a manufacturer to act on his behalf with respect to applicable regulatory requirements in (a) specified jurisdiction(s)
	3.3 **clinical evaluation** assessment and analysis of clinical evidence pertaining to a medical device to verify the clinical safety and performance of the device when used as intended by the manufacturer
3.4 **customer complaint** written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety or performance of a medical device that has been placed on the market	**3.4** **complaint** written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, usability, safety or performance of a medical device that has been released from the organization's control or a service that affects the use of such medical devices
	3.5 **distributor**

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	any natural or legal person in the supply chain who, on their own behalf, furthers the availability of a medical device to the end user. [SOURCE: GHTF/SG1/N055, definition 5.3] Note 1 to entry: More than one distributor may be involved in the supply chain. Note 2 to entry: Persons in the supply chain involved in activities such as storage and transport on behalf of the manufacturer, importer or distributor, are not distributors under this definition.
3.5 **implantable medical device** medical device intended – to be totally or partially introduced into the human body or a natural orifice, or – to replace an epithelial surface or the surface of the eye, by surgical intervention, and which is intended to remain after the procedure for at least 30 days, and which can only be removed by medical or surgical intervention	**3.6** **implantable medical device** medical device intended to: • be totally or partially introduced into the human body or a natural orifice, or • replace an epithelial surface or the surface of the eye, and is intended to remain after the procedure for at least 30 days, and which can only be removed by medical or surgical intervention
	3.7 **importer** any natural or legal person with responsibility to first make a medical device manufactured in one jurisdiction available in another specified jurisdiction Note to entry: A distributor might also act as an importer where it is the first recipient of product from the manufacturer in a particular country
3.6 **labelling** written, printed or graphic matter – affixed to a medical device or any of its containers or wrappers, or – accompanying a medical device, related to identification, technical description, and use of the medical device, but excluding shipping documents NOTE Some regional and national regulations refer to “labelling” as “information supplied by	**3.8** **labelling** written, printed, graphic or electronic information: • affixed to a medical device or any of its containers or wrappers, • accompanying a medical device, or • provided for a medical device by other means related to the identification, technical description, intended purpose and proper

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the manufacturer.”	use of the medical device, but excluding shipping documents NOTE to entry: Applicable regulatory requirements refer to “labelling” as “information supplied by the manufacturer.” This could include advertising, or marketing information

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	3.9 **life-cycle** all phases in the life of a medical device, from the initial conception to final decommissioning and disposal. [SOURCE: ISO 14971:2007, definition 2.7]
	3.10 **manufacturer** any natural or legal person with responsibility for design or manufacture of a medical device with the intention of making the medical device available for use, under their name; whether or not such a medical device is designed or manufactured by that person or on their behalf by another person(s) Note 1 to entry: The definition of the "medical device manufacturer" differs from nation to nation and region to region. The organization needs to understand how the definition in the Standard will be interpreted in light of regulatory definitions for "medical device manufacturer" or equivalent term in the various nations and regions in which its medical devices are sold. Note 2 to entry: This 'natural or legal person' has ultimate legal responsibility for ensuring compliance with applicable regulatory requirements for the medical device in the countries or jurisdictions where it is intended to be made available or sold, unless this responsibility is specifically imposed on another person by the Regulatory Authority (RA) within that jurisdiction. Note 3 to entry: The manufacturer's responsibilities are described in applicable regulatory requirements. These responsibilities might include meeting both pre-market requirements and post-market requirements, such as adverse event reporting and notification of corrective actions. Note 4 to entry: 'Design or manufacture', as referred to in the above definition, may include specification development, production, fabrication, assembly, processing, packaging, repackaging, labelling, relabelling, sterilization, installation, or remanufacturing of a medical device; or putting a collection of medical devices, and possibly other products, together for a medical purpose. Note 5 to entry: Any person who assembles or adapts a medical device that has already been supplied by another person for an individual patient, in accordance with the instructions for use, is not the manufacturer, provided the assembly or adaptation does not

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	change the intended use of the medical device. Note 6 to entry: Any person who changes the intended use of, or modifies, a medical device without acting on behalf of the original manufacturer and who makes it available for use under his own name, should be considered the manufacturer of the modified medical device. Note 7 to entry: An authorized representative, distributor or importer who only adds its own address and contact details to the medical device or the packaging, without covering or changing the existing labelling, is not considered a manufacturer. Note 8 to entry: To the extent that an accessory is subject to the applicable regulatory requirements of a medical device, the person responsible for the design or manufacture of that accessory is considered to be a manufacturer. [Based on GHTF/SG1/N055:2009, definition 5.1].
3.7 **medical device** any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of • diagnosis, prevention, monitoring, treatment or alleviation of disease, • diagnosis, monitoring, treatment, alleviation of or compensation for an injury, • investigation, replacement, modification, or support of the anatomy or of a physiological process, • supporting or sustaining life, • control of conception, • disinfection of medical devices, • providing information for medical purposes by means of in vitro examination of specimens derived fromthe human body, and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means. NOTE This definition has been developed by the Global Harmonization Task Force (GHTF). See	**3.11** **medical device** any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of: • diagnosis, prevention, monitoring, treatment or alleviation of disease, • diagnosis, monitoring, treatment, alleviation of or compensation for an injury, • investigation, replacement, modification, or support of the anatomy or of a physiological process, • supporting or sustaining life, • control of conception, • disinfection of medical devices, or • providing information for medical purposes by means of in vitro

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bibliographicreference [15].	examination of specimens derived from the human body and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means NOTE to entry: Products which might be considered to be medical devices in some jurisdictions but not in others include: • disinfection substances, • aids for persons with disabilities, • devices incorporating animal or human tissues, • devices for in-vitro fertilization or assisted reproduction technologies. [SOURCE: Based on GHTF/SG1/N071 2012, definition 5.1]

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	3.12 **performance evaluation** assessment and analysis of data to establish or verify the ability of an in vitro diagnostic medical device to achieve its intended use
	3.13 **post market surveillance** systematic process to collect and analyse experience gained from medical devices which have been placed on the market
	3.14 **risk** combination of the probability of occurrence of harm and the severity of that harm [SOURCE: ISO 14971:2007, definition 2.16]
	3.15 **risk management** systematic application of management policies, procedures, and practices to the tasks of analyzing, evaluating, controlling, and monitoring risk [SOURCE: ISO 14971:2007, definition 2.22]
3.8 **sterile medical device** category of medical device intended to meet the requirements for sterility NOTE The requirements for sterility of a medical device might be subject to national or regional regulations or standards.	**3.16** **sterile medical device** medical device intended to meet the requirements for sterility NOTE to entry: The requirements for sterility of a medical device might be subject to applicable regulatory requirements or standards.
4 Quality management system **4.1 General requirements** The organization shall establish, document, implement and maintain a quality management system and maintain its effectiveness in accordance with the	**4 Quality management system** **4.1 General requirements** **4.1.1** The organization shall document a quality management system and maintain its effectiveness in accordance with the requirements of this International Standard and applicable regulatory requirements.

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requirements of this International Standard. The organization shall a) identify the processes needed for the quality management system and their application throughout the organization (see 1.2), b) determine the sequence and interaction of these processes, c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective, d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes, e) monitor, measure and analyse these processes, and f) implement actions necessary to achieve planned results and maintain the effectiveness of these processes. These processes shall be managed by the organization in accordance with the requirements of this International Standard. Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system (see 8.5.1). NOTE Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement.	The organization shall establish, implement and maintain any requirement, procedure, activity or special arrangement required by this International Standard and applicable regulatory requirements. The organization shall document the role(s) undertaken by the organization under the applicable regulatory requirements. NOTE Roles undertaken by the organization might include manufacturer, authorized representative, importer, distributor, specification developer or designer of medical device. **4.1.2** The organization shall: a) determine the processes needed for the quality management system and the application of these processes throughout the organization taking into account the roles undertaken by the organization, b) apply a risk based approach to the appropriate processes needed for the quality management system, and c) determine the sequence and interaction of these processes. NOTE Processes needed for the quality management system referred to above include processes for management activities, provision of resources, product realization, and measurement, analysis, and improvement, including post market surveillance. **4.1.3** For each quality management system process, the organization shall: a) determine criteria and methods needed to ensure that both the operation and control of these processes are effective; b) ensure the availability of resources and information necessary to support the operation and monitoring of these processes; c) implement actions necessary to achieve planned results and maintain the effectiveness of these processes; d) monitor, measure as appropriate, and analyse these processes; and e) establish and maintain records needed to demonstrate conformance to this

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	International Standard and compliance with applicable regulatory requirements (see 4.2.4). **4.1.4** The organization shall manage these quality management system processes in accordance with the requirements of this International Standard and applicable regulatory requirements. Changes to be made to these processes shall be: a) evaluated for their impact on the quality management system b) evaluated for their impact on the medical devices produced under this quality management system, and c) controlled in accordance with the requirements of this International Standard and applicable regulatory requirements. **4.1.5** When an organization chooses to outsource any process that affects product conformity with requirements, the organization shall monitor and ensure control over such processes. The controls shall be proportional with the risk involved and the ability of the external party to meet the requirements and shall include written quality agreements. NOTE 1 An "outsourced process" is a process that the organization needs for its quality management system and which the organization chooses to have performed by an external party. NOTE 2 Outsourcing processes does not absolve the organization of the responsibility of conformity to this International Standard and to customer and applicable regulatory requirements. The type and extent of control to be applied to the outsourced processes can be influenced by factors such as: a) The potential impact of the outsourced process on the organization's capability to provide product that conforms to requirements, b) The extent to which the control for the process is shared, and c) The capability of achieving the necessary control through the application of 7.4. **4.1.6** The organization shall document procedures for the validation of the application of computer software used in the quality management system. Such software applications shall be validated for their intended use prior to initial use

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	and, as appropriate, after changes to such software or its application. The specific approach and activities associated with software validation and re-validation shall be proportional with the risk associated with the use of the software. Records of such activities shall be maintained (see 4.2.4)
4.2 Documentation requirements **4.2.1 General** The quality management system documentation shall include a) documented statements of a quality policy and quality objectives, b) a quality manual, c) documented procedures required by this International Standard, d) documents needed by the organization to ensure the effective planning, operation and control of its processes, e) records required by this International Standard (see 4.2.4), and f) any other documentation specified by national or regional regulations. Where this International Standard specifies that a requirement, procedure, activity or special arrangement be "documented", it shall, in addition, be implemented and maintained. For each type or model of medical device, the organization shall establish and maintain a file either containing or identifying documents defining product specifications and quality management system requirements (see 4.2.3). These documents shall define the complete manufacturing process and, if applicable, installation and servicing. NOTE 1 The extent of the quality management system documentation can differ from one organization to another due to a) the size of the organization and type of activities, b) the complexity of processes and their interactions, and	**4.2 Documentation requirements** **4.2.1.1** The quality management system documentation (see 4.2.3) shall include: a) documented statements of a quality policy and quality objectives, b) a quality manual, c) documented procedures and records required by this International Standard, d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation, and control of its processes, and e) any other documentation specified by applicable regulatory requirements. NOTE 1 The documentation can be in any form or type of medium. NOTE 2 The extent of the quality management system documentation can differ from one organization to another due to: • the size of the organization and type of activities, • the complexity of processes and their interactions, • the competence of personnel, and • the product and process risks. **4.2.1.2** For each medical device or medical device family, the organization shall establish and maintain a file(s) either containing or referencing documents generated to demonstrate compliance to the requirement of this International Standard and applicable regulations. The content of this(ese) file(s) shall include

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c) the competence of personnel. NOTE 2 The documentation can be in any form or type of medium.	but is(are) not limited to: a) general description of the medical device, intended use/purpose, and labeling including any instructions for use; b) product, packaging, storage, and distribution specifications; c) manufacturing procedures and specifications; d) measuring and monitoring procedures; e) traceability of changes made to the medical device during the lifetime of the medical device; and, f) as appropriate, installation and servicing activities.
4.2.2 Quality manual The organization shall establish and maintain a quality manual that includes a) the scope of the quality management system, including details of and justification for any exclusion and/or non-application (see 1.2), b) the documented procedures established for the quality management system, or reference to them, and c) a description of the interaction between the processes of the quality management system. The quality manual shall outline the structure of the documentation used in the quality management system.	**4.2.2 Quality manual** The organization shall document a quality manual that includes: a) the scope of the quality management system, including details of and justification for any exclusion or non-application; b) the documented procedures established for the quality management system, or reference to them; and c) a description of the interaction between the processes of the quality management system. The quality manual shall outline the structure of the documentation used in the quality management system.
4.2.3 Control of documents Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4. A documented procedure shall be established to define the controls needed a) to review and approve documents for adequacy prior to issue, b) to review and update as necessary and re-approve documents, c) to ensure that changes and the current revision status of documents are	**4.2.3 Control of documents** Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4. A documented procedure shall be established to define the controls needed to: a) review and approve documents for adequacy prior to issue, b) review and update as necessary and re-approve documents, c) ensure that changes and the current revision status of documents are

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identified, d) to ensure that relevant versions of applicable documents are available at points of use, e) to ensure that documents remain legible and readily identifiable, f) to ensure that documents of external origin are identified and their distribution controlled, and g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose. The organization shall ensure that changes to documents are reviewed and approved either by the original approving function or another designated function which has access to pertinent background information upon which to base its decisions. The organization shall define the period for which at least one copy of obsolete controlled documents shall be retained. This period shall ensure that documents to which medical devices have been manufactured and tested are available for at least the lifetime of the medical device as defined by the organization, but not less than the retention period of any resulting record (see 4.2.4), or as specified by relevant regulatory requirements.	identified, d) ensure that relevant versions of applicable documents are available at points of use, e) ensure that documents remain legible and readily identifiable, f) ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled, g) prevent deterioration or loss of documents, and h) prevent the unintended use of obsolete documents and to apply suitable identification to them. The organization shall ensure that changes to documents are reviewed and approved either by the original approving function or another designated function that has access to pertinent background information upon which to base its decisions. The organization shall define the period for which at least one copy of obsolete documents shall be retained. This period shall ensure that documents to which medical devices have been manufactured and tested are available for at least the lifetime of the medical device as defined by the organization, but not less than the retention period of any resulting record (see 4.2.4), or as specified by applicable regulatory requirements.
4.2.4 Control of records Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records. The organization shall retain the records for a period of time at least equivalent to the lifetime of the medical device as defined by the organization, but not less than two years from the date of product release by the organization or as specified by relevant regulatory requirements.	**4.2.4 Control of records** Records shall be maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. The organization shall document procedures to define the controls needed for the identification, storage, security and integrity, retrieval, retention time and disposition of records. The organization shall define methods for protecting confidential health information contained in records taking into account the applicable regulatory requirements.

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	Records shall remain legible, readily identifiable and retrievable. Changes to a record shall remain identifiable. The organization shall retain the records until at least the end of life of the medical device as defined by the organization, or as specified by applicable regulatory requirements, but not less than two years from the date of the creation of the record. NOTE Records can be in any format or type of medium.
5 Management responsibility **5.1 Management commitment** Top management shall provide evidence of its commitment to the development and implementation of the quality management system and maintaining its effectiveness by a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements, b) establishing the quality policy, c) ensuring that quality objectives are established, d) conducting management reviews, and e) ensuring the availability of resources. NOTE For the purposes of this International Standard, statutory requirements are limited to the safety and performance of the medical device only.	**5 Management responsibility** **5.1 Management commitment** Top management shall provide evidence of its commitment to the development and implementation of the quality management system and maintenance of its effectiveness by: a) communicating to the organization the importance of meeting customer as well as applicable regulatory requirements, b) establishing the quality policy, c) ensuring that quality objectives are established, d) conducting management reviews, and e) ensuring the availability of resources
5.2 Customer focus Top management shall ensure that customer requirements are determined and are met (see 7.2.1 and 8.2.1).	**5.2 Customer focus** Top management shall ensure that customer requirements and applicable regulatory requirements are determined and are met.
5.3 Quality policy Top management shall ensure that the quality policy	**5.3 Quality policy** Top management shall ensure that the quality policy:

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a) is appropriate to the purpose of the organization, b) includes a commitment to comply with requirements and to maintain the effectiveness of the quality management system, c) provides a framework for establishing and reviewing quality objectives, d) is communicated and understood within the organization, and e) is reviewed for continuing suitability.	a) is applicable to the purpose of the organization, b) includes a commitment to comply with requirements and to maintain the effectiveness of the quality management system, c) provides a framework for establishing and reviewing quality objectives, d) is communicated and understood within the organization, and e) is reviewed for continuing suitability.
5.4 Planning **5.4.1 Quality objectives** Top management shall ensure that quality objectives, including those needed to meet requirements for product [see 7.1 a)], are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.	**5.4 Planning** **5.4.1 Quality objectives** Top management shall ensure that quality objectives, including those needed to meet applicable regulatory requirements and requirements for product, are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.
5.4.2 Quality management system planning Top management shall ensure that a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.	**5.4.2 Quality management system planning** Top management shall ensure that: a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented. NOTE Quality management system planning normally includes identification and implementation of action items that are intended to accomplish quality objectives, monitoring the progress toward completion of action items, and revision to the planning based on monitoring.
5.5 Responsibility, authority and communication **5.5.1 Responsibility and authority** Top management shall ensure that responsibilities and authorities are defined, documented and communicated within the organization.	**5.5 Responsibility, authority and communication** **5.5.1 Responsibility and authority** Top management shall ensure that responsibilities and authorities are defined, documented, and communicated within the organization.

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Top management shall establish the interrelation of all personnel who manage, perform and verify work affecting quality, and shall ensure the independence and authority necessary to perform these tasks. NOTE National or regional regulations might require the nomination of specific persons as responsible for activities related to monitoring experience from the post-production stage and reporting adverse events (see 8.2.1 and 8.5.1).	Top management shall establish the interrelation of all personnel who manage, perform and verify work affecting quality, and shall ensure the independence and authority necessary to perform these tasks. NOTE Applicable regulatory requirements might prescribe the nomination of specific persons as responsible for activities related to monitoring experience from the post-production stage and reporting adverse events.
5.5.2 Management representative Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes a) ensuring that processes needed for the quality management system are established, implemented and maintained, b) reporting to top management on the performance of the quality management system and any need for improvement (see 8.5), and c) ensuring the promotion of awareness of regulatory and customer requirements throughout the organization. NOTE The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.	**5.5.2 Management representative** Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes: a) ensuring that processes needed for the quality management system are documented, b) reporting to top management on the effectiveness of the quality management system and any need for improvement, and c) ensuring the promotion of awareness of applicable regulatory requirements and quality management system requirements throughout the organization. NOTE The responsibility of a management representative can include liaison with external parties, including regulatory authorities, on matters relating to the quality management system.
5.5.3 Internal communication Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.	**5.5.3 Internal communication** Top management shall ensure that, as appropriate, communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.
5.6 Management review **5.6.1 General**	**5.6 Management review** **5.6.1 General**

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Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. Records from management reviews shall be maintained (see 4.2.4).	Top management shall review the organization's quality management system at documented planned intervals to ensure its continuing suitability, adequacy, and effectiveness. The rationale for the interval shall be recorded (see 4.2.4). The review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. The requirements for the management review shall be documented. Records from management reviews shall be maintained (see 4.2.4).
5.6.2 Review input The input to management review shall include information on a) results of audits, b) customer feedback, c) process performance and product conformity, d) status of preventive and corrective actions, e) follow-up actions from previous management reviews, f) changes that could affect the quality management system, g) recommendations for improvement, and h) new or revised regulatory requirements.	**5.6.2 Review input** The input to management review shall include, but is not limited to, information arising from: a) results of audits, b) feedback as related to requirements in 8.2.1, c) process performance and product conformity, d) preventive and corrective actions, e) follow-up actions from previous management reviews, f) changes that could affect the quality management system, g) recommendations for improvement, and h) applicable new or revised regulatory requirements.
5.6.3 Review output The output from the management review shall include any decisions and actions related to a) improvements needed to maintain the effectiveness of the quality management system and its processes, b) improvement of product related to customer requirements, and c) resource needs.	**5.6.3 Review output** The output from management review shall be recorded (see 4.2.4) and include the input reviewed and any decisions and actions related to: a) improvement needed to maintain the suitability, adequacy, and effectiveness of the quality management system and its processes; b) improvement of product related to customer requirements; c) changes needed to respond to applicable new or revised regulatory requirements; and d) resource needs.

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6 Resource management **6.1 Provision of resources** The organization shall determine and provide the resources needed a) to implement the quality management system and to maintain its effectiveness, and b) to meet regulatory and customer requirements.	**6 Resource management** **6.1 Provision of resources** The organization shall determine and provide the resources needed to: a) implement the quality management system and to maintain its effectiveness, and b) meet applicable regulatory and customer requirements.
6.2 Human resources **6.2.1 General** Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.	**6.2 Human resources** **6.2.1 General** Personnel performing work affecting product safety or performance shall be competent on the basis of appropriate education, training, skills and experience.
6.2.2 Competence, awareness and training The organization shall a) determine the necessary competence for personnel performing work affecting product quality, b) provide training or take other actions to satisfy these needs, c) evaluate the effectiveness of the actions taken, d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and e) maintain appropriate records of education, training, skills and experience (see 4.2.4). NOTE National or regional regulations might require the organization to establish documented procedures for identifying training needs.	**6.2.2 Competence, awareness and training** The organization shall document the process(es) for establishing competence, providing needed training, and ensuring awareness of personnel. The organization shall: a) determine the necessary competence for personnel performing work affecting product safety or performance, b) provide training or take other actions to achieve or maintain the necessary competence, c) evaluate the effectiveness of the actions taken, d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and e) maintain appropriate records of education, training, skills and experience (see 4.2.4). NOTE The methodology used to check effectiveness is proportional with the risk

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	associated with the work for which the training or other action is being provided.
6.3 Infrastructure The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable a) buildings, workspace and associated utilities, b) process equipment (both hardware and software), and c) supporting services (such as transport or communication). The organization shall establish documented requirements for maintenance activities, including their frequency, when such activities or lack thereof can affect product quality. Records of such maintenance shall be maintained (see 4.2.4).	**6.3 Infrastructure** **6.3.1** The organization shall document the infrastructure needed to provide the controlled work environment, to achieve conformity to product requirements, prevent product mix-up and ensure orderly handling of product. Infrastructure includes, as appropriate: a) buildings, workspace and associated utilities, b) process equipment (both hardware and software), and c) supporting services (such as transport, communication, or information systems). **6.3.2** The organization shall document requirements for the maintenance activities, including the interval of performing the maintenance activities, when such maintenance activities, or lack thereof, can affect product safety or performance. As appropriate, the documentation requirements shall apply to equipment used: a) in production, b) for the control of the work environment, and c) in testing. Records of such maintenance shall be maintained (see 4.2.4).
6.4 Work environment The organization shall determine and manage the work environment needed to achieve conformity to product requirements. The following requirements shall apply. a) The organization shall establish documented requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could adversely affect the quality of the product (see 7.5.1.2.1). b) If work environment conditions can have an adverse effect on product quality, the organization shall establish documented requirements for the work	**6.4 Work environment** **6.4.1 General** **6.4.1.1** The organization shall document the work environment needed to achieve conformity to product requirements. **6.4.1.2** If the work environment can have an adverse effect on product safety or performance, the organization shall document: a) requirements for the work environment, and b) procedures to monitor and control these work environment conditions.

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environment conditions and documented procedures or work instructions to monitor and control these work environment conditions (see 7.5.1.2.1). c) The organization shall ensure that all personnel who are required to work temporarily under special environmental conditions within the work environment are appropriately trained or supervised by a trained person [see 6.2.2 b)]. d) If appropriate, special arrangements shall be established and documented for the control of contaminated or potentially contaminated product in order to prevent contamination of other product, the work environment or personnel (see 7.5.3.1)	NOTE 1 Work environment includes, but is not limited to, areas of infrastructure for production, inspection, storage and distribution. The term work environment relates to those conditions under which work is performed including physical, environmental and other factors (such as noise, temperature, humidity, lighting or weather). NOTE 2 For additional information related to cleanrooms and associated controlled environments see for example ISO 14644 series. **6.4.1.3** The organization shall: a) document requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could affect product safety or performance, and b) ensure that all personnel who are required to work temporarily under special environmental conditions within the work environment are appropriately trained or supervised by a trained person. **6.4.1.4** As appropriate, special arrangements shall be documented for the control of contaminated or potentially contaminated product in order to prevent contamination of the work environment, personnel, or product. NOTE Examples of special arrangements can include controlled and secured access, appropriate sanitation and utilities, appropriate physical separation of areas.
	6.4.2 Particular requirements for sterile medical devices In addition to 6.4.1, the organization shall establish the requirements for the work environment, taking into account the nature of the manufacturing process, in order to: a) prevent contamination with particulate matter or microorganisms, and b) maintain the degree of cleanliness during assembly or packaging operations.

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7 Product realization **7.1 Planning of product realization** The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1). In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product; b) the need to establish processes, documents, and provide resources specific to the product; c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4). The output of this planning shall be in a form suitable for the organization's method of operations. The organization shall establish documented requirements for risk management throughout product realization. Records arising from risk management shall be maintained (see 4.2.4). NOTE 1 A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan. NOTE 2 The organization may also apply the requirements given in 7.3 to the development of product realization processes. NOTE 3 See ISO 14971 for guidance related to risk management.	**7 Product realization** **7.1 Planning of product realization** The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system. The organization shall document a process(es) for risk management throughout product realization. Records of risk management activities shall be maintained (see 4.2.4). In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product; b) the need to establish processes, documents (see 4.2.3), and provide resources specific to the product, including infrastructure and work environment; c) required verification, validation and revalidation, monitoring, measurement, inspection and test activities, handling, storage, traceability specific to the product and the criteria for product acceptance; and d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4). The output of this planning shall be in a form suitable for the organization's method of operations. NOTE 1 A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan. NOTE 2 The organization may also apply the requirements given in 7.3 to the development

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	of product realization processes. NOTE 3 For information related to risk management see other documents, for example ISO 14971. NOTE 4 For information related to software life cycle processes see other documents, for example IEC/ISO 62304.
7.2 Customer-related processes **7.2.1 Determination of requirements related to the product** The organization shall determine a) requirements specified by the customer, including the requirements for delivery and post-delivery activities, b) requirements not stated by the customer but necessary for specified or intended use, where known, c) statutory and regulatory requirements related to the product, and d) any additional requirements determined by the organization	**7.2 Customer-related processes** **7.2.1 Determination of requirements related to the product** The organization shall determine: a) requirements specified by the customer, including the requirements for delivery and post-delivery activities, b) requirements not stated by the customer but necessary for specified or intended use, as known, c) applicable regulatory requirements related to the product, d) any user training needed to ensure specified performance and safe use of the product, and e) any additional requirements determined by the organization. NOTE Post-delivery activities include, for example, actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.
7.2.2 Review of requirements related to the product The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that a) product requirements are defined and documented, b) contract or order requirements differing from those previously expressed are	**7.2.2 Review of requirements related to the product** The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that: a) product requirements are defined and documented,

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resolved, and c) the organization has the ability to meet the defined requirements. Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4). Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance. Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements. NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material.	b) contract or order requirements differing from those previously expressed are resolved, c) applicable regulatory requirements are met, d) any user training identified per requirements of 7.2.1 is available, and e) the organization has the ability to meet the defined requirements. Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4). When the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance. When product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.
7.2.3 Customer communication The organization shall determine and implement effective arrangements for communicating with customers in relation to a) product information, b) enquiries, contracts or order handling, including amendments, c) customer feedback, including customer complaints (see 8.2.1), and d) advisory notices (see 8.5.1).	**7.2.3 Customer communication** **7.2.3.1 Customer communication** The organization shall document arrangements for communicating with customers in relation to: a) product information, b) enquiries, contracts or order handling, including amendments, c) customer feedback, including complaints, and d) advisory notices. **7.2.3.2 Communication with regulatory authorities** As appropriate, the organization shall communicate with regulatory authorities in accordance with planned arrangements.
7.3 Design and development	**7.3 Design and development**

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7.3.1 Design and development planning The organization shall establish documented procedures for design and development. The organization shall plan and control the design and development of product. During the design and development planning, the organization shall determine a) the design and development stages, b) the review, verification, validation and design transfer activities (see Note) that are appropriate at each design and development stage, and c) the responsibilities and authorities for design and development. The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility. Planning output shall be documented, and updated as appropriate, as the design and development progresses (see 4.2.3). NOTE Design transfer activities during the design and development process ensure that design and development outputs are verified as suitable for manufacturing before becoming final production specifications.	**7.3.1 General** The organization shall document procedures for design and development. **7.3.2 Design and development planning** The organization shall plan and control the design and development of product. Planning documents shall be maintained and updated as appropriate, as the design and development progresses. During design and development planning, the organization shall document: a) the design and development stages, b) the review(s) and decisions needed at each design and development stage, c) the verification, validation, and design transfer activities that are appropriate at each design and development stage, d) the responsibilities and authorities for design and development, e) the methods to ensure traceability of design and development outputs to design and development inputs, and f) the resources needed including necessary competence of personnel. NOTE Design and development review, verification and validation have distinct purposes. They can be conducted and recorded separately or in any combination, as suitable for the product and the organization.
7.3.2 Design and development inputs Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include a) functional, performance and safety requirements, according to the intended use, b) applicable statutory and regulatory requirements, c) where applicable, information derived from previous similar designs, d) other requirements essential for design and development, and e) output(s) of risk management (see 7.1).	**7.3.3 Design and development inputs** Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include: a) functional, performance, usability and safety requirements, according to the intended use, b) applicable regulatory requirements and standards, c) applicable output(s) of risk management,

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These inputs shall be reviewed for adequacy and approved. Requirements shall be complete, unambiguous and not in conflict with each other.	d) as appropriate, information derived from previous similar designs, and e) other requirements essential for design and development. These inputs shall be reviewed for adequacy and approved. Requirements shall be complete, unambiguous, able to be verified or validated, and not in conflict with each other. NOTE For information related to usability see other documents, for example ISO/IEC 62366.
7.3.3 Design and development outputs The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release. Design and development outputs shall a) meet the input requirements for design and development, b) provide appropriate information for purchasing, production and for service provision, c) contain or reference product acceptance criteria, and d) specify the characteristics of the product that are essential for its safe and proper use. Records of the design and development outputs shall be maintained (see 4.2.4). NOTE Records of design and development outputs can include specifications, manufacturing procedures, engineering drawings, and engineering or research logbooks.	**7.3.4 Design and development outputs** The outputs of design and development shall be in a form suitable for verification against the design and development input and shall be approved prior to release. Design and development outputs shall: a) meet the input requirements for design and development, b) provide appropriate information for purchasing, production and service provision, c) contain or reference product acceptance criteria, and d) specify the characteristics of the product that are essential for its safe and proper use. Records of the design and development outputs shall be maintained (see 4.2.4). NOTE 1 Information for production and service provision can include details for the preservation of product. NOTE 2 Records of design and development outputs can include, but are not limited to specifications, manufacturing procedures, engineering drawings, source code, and engineering or research logbooks.

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7.3.4 Design and development review At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1) a) to evaluate the ability of the results of design and development to meet requirements, and b) to identify any problems and propose necessary actions. Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed, as well as other specialist personnel (see 5.5.1 and 6.2.1). Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4).	**7.3.5 Design and development review** At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements to: a) evaluate the ability of the results of design and development to meet requirements, and b) identify and propose necessary actions. Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed, as well as other specialist personnel. Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4). NOTE Applicable regulatory requirements might require participation in the design review by a person independent of the design stage under review.
7.3.5 Design and development verification Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4).	**7.3.6 Design and development verification** Design and development verification shall be performed in accordance with planned arrangements to ensure that the design and development outputs have met the design and development input requirements. The organization shall document verification plans that include, as appropriate, methods, acceptance criteria, and sample size(s). If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), verification shall include confirmation that the design outputs meet design inputs when connected or interfaced. Records of the results and conclusions of the verification including, as appropriate, rationale for sample size and necessary actions shall be maintained (see 4.2.3 and

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	4.2.4). NOTE Applicable regulatory requirements might have additional verification requirements.
7.3.6 Design and development validation Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use. Validation shall be completed prior to the delivery or implementation of the product (see Note 1). Records of the results of validation and any necessary actions shall be maintained (see 4.2.4). As part of design and development validation, the organization shall perform clinical evaluations and/or evaluation of performance of the medical device, as required by national or regional regulations (see Note 2). NOTE 1 If a medical device can only be validated following assembly and installation at point of use, delivery is not considered to be complete until the product has been formally transferred to the customer. NOTE 2 Provision of the medical device for purposes of clinical evaluations and/or evaluation of performance is not considered to be delivery.	**7.3.7 Design and development validation** Design and development validation shall be performed in accordance with planned arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use. Validation shall be completed prior to formal transfer of the product to the customer. The organization shall document validation plans that include, as appropriate, methods, acceptance criteria, and sample size(s). Design validation shall be conducted on representative product. The rationale for the choice of product used for validation shall be recorded (see 4.2.4). As part of design and development validation, the organization shall perform clinical evaluations or performance evaluations of the medical device in accordance with applicable regulatory requirements. If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), validation shall include confirmation that the requirements for the specified application or intended use have been met when so connected or interfaced. Records of the results and conclusion of validation including, as appropriate, rationale for sample size any necessary actions shall be maintained (see 4.2.3 and 4.2.4). NOTE 1 For some medical devices, validation can only be performed following assembly and installation at point of use. NOTE 2 Provision of the medical device for purposes of clinical evaluations or performance

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	evaluation is not considered to be formal transfer to the customer. NOTE 3 Representative product includes initial production units, lots, or batches or their equivalents.
	7.3.8 Design and Development Transfer The organization shall document transfer plans by considering the following, as appropriate, and not limited to: a) product specifications, b) process specifications and process validation(s), c) work environment, d) supplier ability to fulfill agreed requirements, e) personnel competence, f) installation, and g) service. Design and development transfer shall be performed in accordance with planned arrangements and documented procedures to ensure that design and development outputs are verified as suitable for manufacturing before becoming final production specifications and that production capability can meet product requirements. Results and conclusions of the transfer shall be recorded (see 4.2.4).
7.3.7 Control of design and development changes Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions shall be	**7.3.9 Control of design and development changes** **7.3.9.1** The organization shall establish processes to control design and development changes that affect the design of the medical device and determine the significance of the change to product function, performance, safety, and applicable regulatory requirements for the intended use and take appropriate action. **7.3.9.2** Design and development changes shall be identified and records maintained. Before implementation, the changes shall be:

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maintained (see 4.2.4).	a) reviewed, b) verified, c) validated, as appropriate, and d) approved. **7.3.9.3** The review of design and development changes shall include evaluation of the effect of the changes on: a) constituent parts and product in process or already delivered, b) outputs of risk management, and c) product realization processes. **7.3.9.4** Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).
	7.3.10 Design and development records The organization shall maintain a design and development file for each medical device or medical device family including or referencing records generated to demonstrate compliance to the requirements for design and development, including design and development changes.
7.4 Purchasing **7.4.1 Purchasing process** The organization shall establish documented procedures to ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product. The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection,	**7.4 Purchasing** **7.4.1 Purchasing process** **7.4.1.1 General** The organization shall document procedures (see 4.2.3) to ensure that purchased product conforms to specified purchasing information. **7.4.1.2 Supplier approval** The organization shall plan the supplier selection, and shall establish selection and evaluation criteria, evaluate and approve suppliers based on their ability to meet

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evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).	defined criteria and supply product in accordance with the organization's requirements and applicable regulatory requirements. The established criteria for selection and evaluation shall be: a) based on the capability or performance of the supplier, b) based on the effect of the purchased product on the safety and performance of the medical device c) proportional to the risk associated with the medical device. **7.4.1.3 Monitoring of suppliers** The organization shall plan the supplier monitoring and re-evaluation criteria. A supplier's performance in meeting requirements for the purchased product shall be monitored and the results of the monitoring shall provide an input into the supplier re-evaluation process. Non fulfilment of purchasing specifications and expectations shall be handled with the supplier proportional to the risk associated with the purchased product and compliance with applicable regulatory requirements. **7.4.1.4 Supplier records** Records of the results of evaluation and monitoring, re-evaluation of supplier performance, and any necessary actions arising from these shall be maintained (see 4.2.4).
7.4.2 Purchasing information Purchasing information shall describe the product to be purchased, including where appropriate a) requirements for approval of product, procedures, processes and equipment, b) requirements for qualification of personnel, and c) quality management system requirements. The organization shall ensure the adequacy of specified purchase requirements prior	**7.4.2 Purchasing information** Purchasing information shall describe or reference the product to be purchased, including as appropriate: a) product specifications; b) requirements for product acceptance, procedures, processes and equipment; c) requirements for qualification of personnel; and d) quality management system requirements.

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to their communicationto the supplier. To the extent required for traceability given in 7.5.3.2, the organization shall maintain relevant purchasing information, i.e. documents (see 4.2.3) and records (see 4.2.4).	The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier. Purchasing information shall include, as applicable, a written agreement that the suppliers notify the organization of changes in the purchased product prior to implementation of any changes that affect the ability of the purchased product to meet specified purchase requirements. To the extent required for traceability given in 7.5.3.2, the organization shall maintain relevant purchasing information, i.e. documents (see 4.2.3) and records (see 4.2.4).
7.4.3 Verification of purchased product The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements. Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information. Records of the verification shall be maintained (see 4.2.4).	**7.4.3 Verification of purchased product** The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchasing requirements. The extent of verification activities shall be based on the result of the evaluation and re-evaluation of the supplier and proportional to the risks associated with the purchased product. When the organization becomes aware of any changes to the purchased product, the organization shall determine whether these changes affect the product realization process or the medical device. When the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information. Records of the verification shall be maintained (see 4.2.4).
7.5 Production and service provision	**7.5 Production and service provision**

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7.5.1 Control of production and service provision **7.5.1.1 General requirements** The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable a) the availability of information that describes the characteristics of the product, b) the availability of documented procedures, documented requirements, work instructions, and reference materials and reference measurement procedures as necessary, c) the use of suitable equipment, d) the availability and use of monitoring and measuring devices, e) the implementation of monitoring and measurement, f) the implementation of release, delivery and post-delivery activities, and g) the implementation of defined operations for labelling and packaging. The organization shall establish and maintain a record (see 4.2.4) for each batch of medical devices that provides traceability to the extent specified in 7.5.3 and identifies the amount manufactured and amount approved for distribution. The batch record shall be verified and approved. NOTE A batch can be a single medical device.	**7.5.1 Control of production and service provision** **7.5.1.1 General requirements** Production and service provision shall be planned, carried out, monitored and controlled to ensure that medical devices conform to specification. Production controls shall include, but are not limited to, as appropriate: a) the documentation of procedures and methods relevant for the control of production (see 4.2.3), b) equipment qualification, c) the implementation of monitoring and measurement of process parameters and product characteristics, d) the availability and use of monitoring and measuring equipment, e) the implementation of defined operations for labelling and packaging, and f) the implementation of product release, delivery and post-delivery activities The organization shall establish and maintain a record (see 4.2.4) for each batch of medical devices that provides traceability to the extent specified in 7.5.3 and identifies the amount manufactured and amount approved for distribution. The record shall be verified and approved. NOTE A batch can be a single medical device.
7.5.1.2 Control of production and service provision — Specific requirements **7.5.1.2.1 Cleanliness of product and contamination control** The organization shall establish documented requirements for cleanliness of product if a) product is cleaned by the organization prior to sterilization and/or its use, or b) product is supplied non-sterile to be subjected to a cleaning process prior to sterilization and/or its use, or c) product is supplied to be used non-sterile and its cleanliness is of significance in	**7.5.1.2 Control of production and service provision — Specific requirements** **7.5.1.2.1 Cleanliness of product and contamination control** The organization shall document requirements for cleanliness or contamination control of product if: a) product is cleaned by the organization prior to sterilization or its use; b) product cannot be cleaned prior to sterilization or its use, and its cleanliness is of significance in use; c) product is supplied non-sterile to be subjected to a cleaning process prior

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use, or d) process agents are to be removed from product during manufacture. If product is cleaned in accordance with a) or b) above, the requirements contained in 6.4 a) and 6.4 b) do not apply prior to the cleaning process. **7.5.1.2.2 Installation activities** If appropriate, the organization shall establish documented requirements which contain acceptance criteria for installing and verifying the installation of the medical device. If the agreed customer requirements allow installation to be performed other than by the organization or its authorized agent, the organization shall provide documented requirements for installation and verification. Records of installation and verification performed by the organization or its authorized agent shall be maintained (see 4.2.4). **7.5.1.2.3 Servicing activities** If servicing is a specified requirement, the organization shall establish documented procedures, work instructions and reference materials and reference measurement procedures, as necessary, for performing servicing activities and verifying that they meet the specified requirements. Records of servicing activities carried out by the organization shall be maintained (see 4.2.4).	to sterilization or its use; d) product is supplied to be used non-sterile, and its cleanliness is of significance in use; or e) process agents are to be removed from product during manufacture. If product is cleaned in accordance with a) or c) above, the requirements contained in 6.4.1.2 a) and 6.4.1.2 b) do not apply prior to the cleaning process. **7.5.1.2.2 Installation activities** The organization shall document requirements for installation and acceptance criteria for installation verification, as appropriate. If the agreed customer requirements allow installation to be performed by an external party other than the organization or its supplier, the organization shall provide documented requirements for installation and verification. Records of installation and verification performed by the organization or its supplier shall be maintained (see 4.2.4). **7.5.1.2.3 Servicing activities** If servicing is a requirement, the organization shall document procedures, reference materials, and reference measurement procedures, as necessary, for performing servicing activities and verifying that they meet the requirements. The organization shall analyse records of servicing activities carried out by the organization or supplier to determine if the information shall be handled as a complaint(s). The organization shall consider records of servicing activities as a source of information to be analysed as appropriate for the improvement process. Records of servicing activities carried out by the organization or its supplier shall be maintained (see 4.2.4).

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NOTE Servicing can include, for example, repair and maintenance.	NOTE Servicing can include, for example, repair and maintenance.
7.5.1.3 Particular requirements for sterile medical devices The organization shall maintain records of the process parameters for the sterilization process which was used for each sterilization batch (see 4.2.4). Sterilization records shall be traceable to each production batch of medical devices (see 7.5.1.1).	**7.5.1.3 Particular requirements for sterile medical devices** The organization shall maintain records of the process parameters for the sterilization process that were used for each sterilization batch (see 4.2.4). Sterilization records shall be traceable to each production batch of medical devices.
7.5.2 Validation of processes for production and service provision **7.5.2.1 General requirements** The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered. Validation shall demonstrate the ability of these processes to achieve planned results. The organization shall establish arrangements for these processes including, as applicable a) defined criteria for review and approval of the processes, b) approval of equipment and qualification of personnel, c) use of specific methods and procedures, d) requirements for records (see 4.2.4), and e) revalidation. The organization shall establish documented procedures for the validation of the application of computer software (and changes to such software and/or its application) for production and service provision that affect the ability of the product to conform to specified requirements. Such software applications shall be validated prior to initial use. Records of validation shall be maintained (see 4.2.4)	**7.5.2 Validation of processes for production and service provision** **7.5.2.1 General requirements** The organization shall validate any processes for production and service provision where the resulting output cannot be or is not verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered. Validation shall demonstrate the ability of these processes to achieve planned results consistently. The organization shall document validation plans that include, as appropriate, methods, acceptance criteria, and sample size(s). The organization shall document procedures for processes to be validated including, as appropriate: a) defined criteria for review and approval of the processes, b) equipment qualification and qualification of personnel, c) use of specific methods and procedures, d) requirements for records (see 4.2.4), e) revalidation, including conditions triggering revalidation, and f) approval of changes to the processes. The organization shall document procedures for the validation of the application

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	of computer software (and changes to such software or its application) for production and service provision that affect the ability of the product to conform to specifications. Such software shall be validated prior to use. Records of the results, conclusion and any necessary actions from the validation shall be maintained (see 4.2.4).
7.5.2.2 Particular requirements for sterile medical devices The organization shall establish documented procedures for the validation of sterilization processes. Sterilization processes shall be validated prior to initial use. Records of validation of each sterilization process shall be maintained (see 4.2.4).	**7.5.2.2 Particular requirements for sterile medical devices** The organization shall document procedures (see 4.2.3) for the validation of sterilization and packaging processes for sterile barrier systems. Packaging processes for sterile barrier systems and sterilization processes shall be validated prior to implementation and following product or process changes, as appropriate. Records of the results, conclusion and any necessary actions from the validation shall be maintained (see 4.2.4) NOTE For additional information related to packaging validation see, for example, ISO 11607-1, ISO 11607-2 and ISO TS 16775.
7.5.3 Identification and traceability **7.5.3.1 Identification** The organization shall identify the product by suitable means throughout product realization, and shall establish documented procedures for such product identification. The organization shall establish documented procedures to ensure that medical devices returned to the organization are identified and distinguished from conforming product [see 6.4 d)].	**7.5.3 Identification and traceability** **7.5.3.1 Identification** As appropriate, the organization shall identify the product by suitable means throughout product realization, and shall document procedures for such product identification. If required by applicable regulatory requirements, the organization shall document a system to assign unique device identification to the medical device. The organization shall document procedures to ensure that medical devices returned to the organization are identified and distinguished from conforming product.

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7.5.3.2 Traceability **7.5.3.2.1 General** The organization shall establish documented procedures for traceability. Such procedures shall define the extent of product traceability and the records required (see 4.2.4, 8.3 and 8.5). Where traceability is a requirement, the organization shall control and record the unique identification of the product (see 4.2.4). NOTE Configuration management is a means by which identification and traceability can be maintained. **7.5.3.2.2 Particular requirements for active implantable medical devices and implantable medical devices** In defining the records required for traceability, the organization shall include records of all components, materials and work environment conditions, if these could cause the medical device not to satisfy its specified requirements. The organization shall require that its agents or distributors maintain records of the distribution of medical devices to allow traceability and that such records are available for inspection. Records of the name and address of the shipping package consignee shall be maintained (see 4.2.4).	**7.5.3.2 Traceability** **7.5.3.2.1 General** The organization shall document procedures and maintain records for traceability (see 4.2.4). These procedures shall define the extent of traceability in accordance with applicable regulatory requirements. Traceability shall enable the organization to investigate problems, including customer complaints, and to implement corrections or corrective actions. The records shall identify where the medical device has been delivered by the organization (see 4.2.4). NOTE The extent of traceability can be in two directions, forward to customers and backward to raw materials, components and processes used in manufacturing. **7.5.3.2.2 Particular requirements for implantable medical devices** In defining the records required for traceability, the organization shall include records of all components, materials and work environment conditions, if these could cause the medical device not to satisfy its specified safety and performance requirements. The organization shall require that its suppliers or distributors maintain records of the distribution of medical devices to allow traceability and that such records are available for inspection. Records of the name and address of the shipping package consignee shall be maintained (see 4.2.4).
7.5.3.3 Status identification The organization shall identify the product status with respect to monitoring and measurement requirements.	**7.5.3.3 Status identification** The organization shall identify the product status with respect to monitoring and measurement requirements throughout product realization. Identification of product status shall be maintained throughout production, storage, installation

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The identification of product status shall be maintained throughout production, storage, installation and servicing of the product to ensure that only product that has passed the required inspections and tests (or released under an authorized concession) is dispatched, used or installed.	and servicing of the product to ensure that only product that has passed the required inspections and tests (or released under an authorized concession) is dispatched, used or installed.
7.5.4 Customer property The organization shall exercise care with customer property while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained (see 4.2.4). NOTE Customer property can include intellectual property or confidential health information.	**7.5.4 Customer property** The organization shall identify, verify, protect, and safeguard customer property provided for use or incorporation into the product while it is under the organization's control or being used by the organization. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer and maintain records (see 4.2.4). NOTE Customer property can include intellectual property or confidential health information
7.5.5 Preservation of product The organization shall establish documented procedures or documented work instructions for preserving the conformity of product during internal processing and delivery to the intended destination. This preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product. The organization shall establish documented procedures or documented work instructions for the control of product with a limited shelf-life or requiring special storage conditions. Such special storage conditions shall be controlled and recorded (see 4.2.4).	**7.5.5 Preservation of product** **7.5.5.1** The organization shall document procedures for preserving the conformity of product to requirements during internal processing, storage, handling, and distribution. Preservation shall apply to the constituent parts of a medical device. NOTE Sterile barrier systems of sterile medical devices are a constituent part of a medical device. **7.5.5.2** The organization shall protect the medical device from alteration, contamination or damage when exposed to expected conditions and hazards during processing, storage, handling, and distribution by: a) Designing and constructing suitable packaging and shipping containers, or b) Documenting requirements for special conditions needed if packaging alone cannot provide the preservation. In case special conditions have to be followed, they shall be controlled and recorded (see 4.2.4).

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	NOTE Examples can include products which require temperature control during transport and storage or products requiring special conditions for processing, storage, handling, and distribution.
7.6 Control of monitoring and measuring devices The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1). The organization shall establish documented procedures to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements. Where necessary to ensure valid results, measuring equipment shall a) be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded; b) be adjusted or re-adjusted as necessary; c) be identified to enable the calibration status to be determined; d) be safeguarded from adjustments that would invalidate the measurement result; e) be protected from damage and deterioration during handling, maintenance and storage. In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained (see 4.2.4). When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.	**7.6 Control of monitoring and measuring devices** The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements as per documented procedures. As necessary to ensure valid results, measuring equipment shall: a) be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards. When no such standards exist, the basis used for calibration or verification shall be recorded (see 4.2.4); b) be adjusted or re-adjusted as necessary; c) have identification in order to determine its calibration status; d) be safeguarded from adjustments that would invalidate the measurement result; and e) be protected from damage and deterioration during handling, maintenance and storage. The organization shall perform calibration or verification in accordance with planned arrangements and documented procedures. In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained (see 4.2.4). When used in the monitoring and measurement of requirements, the ability of computer software to satisfy the intended application shall be confirmed. This

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NOTE See ISO 10012 for guidance related to measurement management systems.	shall be undertaken prior to use and reconfirmed as necessary. NOTE For guidance related to measurement management systems see other documents, for example ISO 10012
8 Measurement, analysis and improvement **8.1 General** The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed a) to demonstrate conformity of the product, b) to ensure conformity of the quality management system, and c) to maintain the effectiveness of the quality management system. This shall include determination of applicable methods, including statistical techniques, and the extent of their use. NOTE National or regional regulations might require documented procedures for implementation and control of the application of statistical techniques.	**8 Measurement, analysis and improvement** **8.1 General** The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed to: a) demonstrate conformity of the product, b) ensure conformity of the quality management system, and c) maintain the effectiveness of the quality management system. This shall include determination of appropriate methods, including statistical techniques, and the extent of their use. NOTE Applicable regulatory requirements might require documented procedures for implementation and control of the application of statistical techniques.
8.2 Monitoring and measurement **8.2.1 Feedback** As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined. The organization shall establish a documented procedure for a feedback system [see 7.2.3 c)] to provide early warning of quality problems and for input into the corrective and preventive action processes (see 8.5.2 and 8.5.3).	**8.2 Monitoring and measurement** **8.2.1 Feedback** **8.2.1.1 General** As one of the measurements of the effectiveness of the quality management system, the organization shall gather and monitor information relating to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined and documented. The organization shall document procedures for the feedback process. This feedback process shall include provisions to gather data from production as well

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If national or regional regulations require the organization to gain experience from the post-production phase, the review of this experience shall form part of the feedback system (see 8.5.1).	as post-production activities. The information gathered in the feedback process shall serve as input into risk management for monitoring and maintaining the product requirements as well as potential input into the product realization processes. If applicable regulatory requirements require the organization to gain specific experience from the post-production phase, the review of this experience shall form part of the feedback process.
	8.2.1.2 Complaint handling and reporting to regulatory authorities **8.2.1.2.1 Complaint handling** The organization shall document procedures for timely complaint handling in accordance with applicable regulatory requirements. These procedures shall include at a minimum requirements and responsibilities for: a) Receiving information, b) Evaluating information to determine if the feedback constitutes a complaint, c) Investigating complaints, d) Determining the need to report the information to the appropriate regulatory authorities, e) Handling of complaint-related product, f) Determining and initiating corrections or corrective actions, and g) Defining requirements for complaint records. If any complaint is not investigated, justification shall be documented. Any correction or corrective action resulting from the complaint handling process shall be documented. If an investigation determines activities outside the organization contributed to the complaint, relevant information shall be exchanged between the organization

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	and the external party involved. Complaint handling records shall be maintained (see 4.2.4). **8.2.1.2.2 Reporting regulatory authorities** If applicable regulatory requirements require notification of complaints that meet specified reporting criteria of adverse events the organization shall document procedures for providing notification to the appropriate regulatory authorities. Records of reporting to regulatory authorities shall be maintained (see 4.2.4).
8.2.2 Internal audit The organization shall conduct internal audits at planned intervals to determine whether the quality management system a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and b) is effectively implemented and maintained. An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work. The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) shall be defined in a documented procedure. The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the	**8.2.2 Internal audit** The organization shall conduct internal audits at planned intervals to determine whether the quality management system: a) conforms to the planned arrangements, to the requirements of this International Standard, to the quality management system requirements established by the organization, and applicable regulatory requirements; and b) is effectively implemented and maintained. The organization shall document a procedure to describe the responsibilities and requirements for planning and conducting audits, establishing records and reporting results. An audit program shall be planned, taking into consideration the status and importance of the processes and area(s) to be audited, as well as the results of previous audits. If changes are made to the planned audit program, the justification for the change shall be recorded (see 4.2.4). The audit criteria, scope, interval and methods shall be defined and recorded (see 4.2.4). The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

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reporting of verification results (see 8.5.2). NOTE See ISO 19011 for guidance related to quality auditing.	Records of the audits and their results, including identification of the processes and areas reviewed and the conclusions, shall be maintained (see 4.2.4). The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results. NOTE For guidance related to auditing see other documents, for example ISO 19011.
8.2.3 Monitoring and measurement of processes The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.	**8.2.3 Monitoring and measurement of processes** The organization shall apply suitable methods for monitoring and, as appropriate, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate. NOTE When determining suitable methods, it is advisable that the organization consider the type and extent of monitoring or measurement appropriate to each of its processes in relation to their impact on the conformity to product requirements and on the effectiveness of the quality management system.
8.2.4 Monitoring and measurement of product **8.2.4.1 General requirements** The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1) and documented procedures (see 7.5.1.1). Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product (see 4.2.4).	**8.2.4 Monitoring and measurement of product** **8.2.4.1 General requirements** The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at applicable stages of the product realization process in accordance with the planned arrangements and documented procedures. Evidence of conformity with the acceptance criteria shall be maintained. As appropriate, records shall identify the test equipment used to perform

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Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed.	measurement activities. The identity of the person(s) authorizing release of product shall be recorded (see 4.2.4). Product release and service delivery shall not proceed until the planned arrangements have been satisfactorily completed.
8.2.4.2 Particular requirement for active implantable medical devices and implantable medical devices The organization shall record (see 4.2.4) the identity of personnel performing any inspection or testing.	**8.2.4.2 Particular requirement for implantable medical devices** The organization shall record the identity of personnel performing any inspection or testing.
8.3 Control of nonconforming product The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure. The organization shall deal with nonconforming product by one or more of the following ways: a) by taking action to eliminate the detected nonconformity; b) by authorizing its use, release or acceptance under concession; c) by taking action to preclude its original intended use or application. The organization shall ensure that nonconforming product is accepted by concession only if regulatoryrequirements are met. Records of the identity of the person(s) authorizing the concession shall be maintained (see 4.2.4). Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4). When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.	**8.3 Control of nonconforming product** **8.3.1 General** The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The organization shall document a procedure to define the controls and related responsibilities and authorities for the identification, documentation, segregation, evaluation, and disposition of nonconforming product. The evaluation of nonconformity shall include a determination of the need for an investigation and notification of any external party responsible for the nonconformity. Nonconforming product shall be considered for corrective action. Records of the nature of the nonconformities and any subsequent action(s) taken, including the evaluation, any investigation and the rationale for decisions shall be maintained (see 4.2.4)

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When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity. If product needs to be reworked (one or more times), the organization shall document the rework process in a work instruction that has undergone the same authorization and approval procedure as the original work instruction. Prior to authorization and approval of the work instruction, a determination of any adverse effect of the rework upon product shall be made and documented (see 4.2.3 and 7.5.1).	
	8.3.2 Actions in response to nonconforming product before delivery As appropriate, the organization shall deal with nonconforming product by one or more of the following ways by: a) taking action to eliminate the detected nonconformity; b) authorizing its use, release or acceptan**c**e under concession; c) taking action to preclude its original intended use or application. The organization shall ensure that nonconforming product is accepted by concession only if the justification is provided, approval(s) are obtained, and applicable regulatory requirements are met. Records of the acceptance by concession and the identity of the person(s) authorizing the concession shall be maintained (see 4.2.4).
	8.3.3 Actions in response to nonconforming product after delivery **8.3.3.1** When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity. Records of actions taken shall be maintained (see 4.2.4). **8.3.3.2**. The organization shall document procedures for the issuance and implementation of advisory notices. These procedures shall be capable of being implemented at any time. Records of actions relating to the issuance and implementation of advisory notices shall be maintained (see 4.2.4).

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	8.3.4 Rework The organization shall perform rework in accordance with documented procedures or work instruction that takes into account the potential adverse effect(s) of the rework on the product. These shall undergo the same review and approval as the original procedure or work instruction. As applicable, after the completion of rework the product shall be retested to ensure that the product meets requirements and applicable regulatory requirements. Records of rework shall be maintained (see 4.2.4)
8.4 Analysis of data The organization shall establish documented procedures to determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate if improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources. The analysis of data shall provide information relating to a) feedback (see 8.2.1), b) conformity to product requirements (see 7.2.1), c) characteristics and trends of processes and products including opportunities for preventive action, and d) suppliers. Records of the results of the analysis of data shall be maintained (see 4.2.4).	**8.4 Analysis of data** The organization shall document procedures to determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate if improvement of the effectiveness of the quality management system can be made. The procedures shall include determination of appropriate methods including statistical techniques and the extent of their use. The analysis of data shall include data generated as a result of monitoring and measurement and from other relevant sources and include, as a minimum, input from: a) feedback, b) conformity to product requirements, c) characteristics and trends of processes and products including opportunities for improvement, d) suppliers, e) audits, and f) service reports, as appropriate. Records of the results of analyses shall be maintained (see 4.2.4).

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8.5 Improvement **8.5.1 General** The organization shall identify and implement any changes necessary to ensure and maintain the continued suitability and effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review. The organization shall establish documented procedures for the issue and implementation of advisory notices. These procedures shall be capable of being implemented at any time. Records of all customer complaint investigations shall be maintained (see 4.2.4). If investigation determines that the activities outside the organization contributed to the customer complaint, relevant information shall be exchanged between the organizations involved (see 4.1). If any customer complaint is not followed by corrective and/or preventive action, the reason shall beauthorized (see 5.5.1) and recorded (see 4.2.4). If national or regional regulations require notification of adverse events that meet specified reporting criteria, the organization shall establish documented procedures to such notification to regulatory authorities.	**8.5 Improvement** **8.5.1 General** The organization shall identify and implement any changes necessary to ensure and maintain the continued suitability and effectiveness of the quality management system as well as product safety and performance through the use of the quality policy, quality objectives, audit results, post market surveillance, analysis of data, corrective and preventive actions and management review.
8.5.2 Corrective action The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.	**8.5.2 Corrective action** The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. . Corrective actions shall be appropriate to the effects of the nonconformities encountered.

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A documented procedure shall be established to define requirements for a) reviewing nonconformities (including customer complaints), b) determining the causes of nonconformities, c) evaluating the need for action to ensure that nonconformities do not recur, d) determining and implementing action needed, including, if appropriate, updating documentation (see 4.2), e) recording of the results of any investigation and of action taken (see 4.2.4), and f) reviewing the corrective action taken and its effectiveness.	The organization shall document a procedure to define requirements for: a) reviewing nonconformities (including complaints); b) determining the causes of nonconformities; c) evaluating the need for action to ensure that nonconformities do not recur; d) planning and documenting action needed and implementing such action in a timely manner, including, as appropriate, updating documentation; e) verifying that the corrective action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device; and f) reviewing the effectiveness of corrective action taken. Records of the results of any investigation and *action taken* shall be maintained (see 4.2.4)
8.5.3 Preventive action The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems. A documented procedure shall be established to define requirements for a) determining potential nonconformities and their causes, b) evaluating the need for action to prevent occurrence of nonconformities, c) determining and implementing action needed, d) recording of the results of any investigations and of action taken (see 4.2.4), and e) reviewing preventive action taken and its effectiveness.	**8.5.3 Preventive action** The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems. The organization shall document a procedure to describe requirements for: a) determining potential nonconformities and their causes, b) evaluating the need for action to prevent occurrence of nonconformities, c) planning and documenting action needed, and implementing such action in a timely manner, including, as appropriate, updating documentation, d) verifying that the action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of products, and e) reviewing the effectiveness of the preventive action taken, as appropriate. Records of the results of any investigations and of action taken shall be maintained

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	(see 4.2.4).

Annex ZA
(informative)

Relationship between this European Standard and the Conformity Assessment Requirements of EU Directive 90/385/EEC(as amended)

ZA.1 General

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means by which a manufacturer may demonstrate conformity, and by which the Notified Body may assess the manufacturer's conformity, with the requirements of Directive 90/385/EEC (as amended) on active implantable medical devices.

Within the limits of the scope of this standard (Clause 1 of EN ISO 13485:201X), compliance with the normative clauses of this standard according to the qualifying remarks presented in Tables ZA.1 and ZA.2 confers presumption of conformity with the requirements on a manufacturer's quality system[1)] as given in Annexes 2 and 5 of that Directive and associated EFTA regulations, once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State. This Annex ZA explains to which requirements, under which conditions and to what extent presumption of conformity can be claimed.

The Conformity Assessment Annexes 2 and 5 of the Directive include description of the regulatory process and activities undertaken by the Notified Body, which both are outside of the scope of EN ISO 13485 and therefore not covered by this standard. Furthermore, the requirements of the Directive refer to an application to a Notified Body, not to the requirement for a quality system as such. Accordingly, coverage of legal requirements can only be presumed to the extent listed in Tables ZA.1 and ZA.2 if an application to a Notified Body:

- contains the necessary quality system documentation;
- has been reviewed and approved by a Notified Body,

and the undertakings listed in the application are correctly executed by the manufacturer.

ZA.2 Relationship with Annex 2 of Directive 90/385/EEC (as amended)

Compliance with EN ISO 13485 does not provide presumption of conformity with all the aspects of Annex 2, as outlined in Table ZA.1. Therefore, a manufacturer or a Notified Body has to take additional provisions to ensure conformity, and claim or certify conformance, with Annex 2 of this Directive. The legal requirements must be examined, applied and verified one by one and the solutions adopted must become part of the quality system in the meaning of the Directive.

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1) This annex uses the term "quality system" as used in the Directive whereas EN ISO 13485 uses the term "quality management system" in accordance with ISO terminology.

Table ZA.1 — Relationship between Annex 2 of Directive 90/385/EEC (as amended) and the clauses of EN ISO 13485

Paragraph of Directive 90/385/EEC, Annex 2	Clause(s) of EN ISO 13485	Comments/Qualifying remarks
3.1 first sentence		Not covered
3.1 second sentence 1st indent		Not covered
3.1 second sentence 2nd indent	4.1, 4.2	Covered provided that the applicable documentation listed below in the comments column of this table is incorporated into the quality system documentation.
3.1 second sentence 3rd indent	4.1, 5.1, 5.4, 5.5, 5.6	Covered
3.1 second sentence 4th indent	4.1, 5.1, 5.4, 5.5, 5.6	Covered
3.1 second sentence 5th indent	7.2.3 c. 8.2.1, 8.3, 8.4, 8.5.1, 8.5.2	Covered in part. Annex 2 has specific expectations on a proactive post market surveillance system, updating of clinical data with post market surveillance information, reporting adverse events and field safety corrective actions
3.2 first paragraph	1.1	Covered provided that the legal requirements are examined, applied and verified, and the solutions adopted become part of the quality system in the meaning of the Directive.
3.2 second paragraph, first sentence	4.1, 4.2	Covered
3.2 second paragraph, second sentence	4.1, 4.2	Covered
3.2 second paragraph, second and third sentences	4.1, 4.2, 7	Covered provided quality management system documentation makes possible a uniform interpretation of the quality policies and procedures, such as quality programmes, quality plans, quality manuals and quality records, and that the applicable documentation listed below is incorporated into the quality system documentation.
3.2 third paragraph (a)	4.2.1, 5.1, 5.3, 5.4.1	Covered
3.2 third paragraph (b)	4.2.2, 5.1.1	Covered
3.2 third paragraph (b) 1st indent	4.2.2, 5.1, 5.5.1, 5.5.2	Covered
3.2 third paragraph (b) 2nd	4.1, 5.6, 7.1, 8.2.2,	Covered provided that the methods and acceptance

Table ZA.1 — Relationship between Annex 2 of Directive 90/385/EEC (as amended) and the clauses of EN ISO 13485

Paragraph of Directive 90/385/EEC, Annex 2	Clause(s) of EN ISO 13485	Comments/Qualifying remarks
indent	8.3, 8.4, 8.5.2, 8.5.3	criteria chosen by the manufacturer ensure that the requirements of the Directive are fulfilled.
3.2 third paragraph (b) 3rd indent	1.2, 4.1, 4.2, 7.4, 8.5.1	Covered.
3.2 third paragraph (c) 1st indent	4.2, 7.3.2, 7.3.3, 7.3.6, 7.3.8	Covered provided that the applicable quality management system documentation includes design specifications identifying standards which will be applied and a description of the solutions adopted to fulfil the essential requirements which apply when harmonized standards are not applied in full,
3.2 third paragraph (c) 2nd indent	7.3.1, 7.3.5, 7.3.6, 7.3.7	Covered
3.2 third paragraph (c) 3rd indent	4.2.1.2	Covered provided that the quality management system documentation includes a statement indicating whether or not the medical device incorporates, as an integral part, a substance or a human blood derivative and the data on the tests conducted in this connection required to assess the safety, quality and usefulness of that substance or human blood derivative, taking account of the intended purpose of the medical device,.
3.2 third paragraph (c) 4th indent	7.3.5, 7.3.8	Covered provided that the quality management system records include the pre-clinical evaluation,
3.2 third paragraph (c) 5th indent	7.3.6	Not covered. 7.3.6 does not include the details of Annex 7
3.2 third paragraph (d) 1st indent	4.2, 6.4, 7.1, 7.4 7.5.1, 7.5.2	Covered provided that the quality management system documentation includes relevant documents and records in regards to sterilization and purchasing
3.2 third paragraph (d) 2nd indent	4.2, 7.5.3,	Covered
3.2 third paragraph (e)	7.1,7.4.3,7.6, 8.2.4	Covered provided that the frequency at which tests are carried out is documented in the quality management system documentation..
6.1	4.2.3, 4.2.4	Not covered. The specific time periods in Directive are not specified.

ZA.3 Relationship with Annex 5 of Directive 90/385/EEC (as amended)

Compliance with EN ISO 13485 does not provide presumption of conformity with all the aspects of Annex 5, as outlined in Table ZA.2. Therefore, a manufacturer or a Notified Body has to take additional provisions to ensure conformity, and claim or certify conformance, with Annex 5 of this Directive. The legal requirements must be examined, applied and verified one by one and the solutions adopted must become part of the quality system in the meaning of the directive.

Table ZA.2 — Relationship between Annex 5 of Directive 90/385/EEC (as amended) and the clauses of EN ISO 13485

Paragraph of Directive 90/385/EEC, Annex 5	Clause(s) of EN ISO 13485	Comments/Qualifying remarks
3.1first paragraph		Not covered
3.1 second paragraph 1st indent		Not covered
3.1 second paragraph 2nd indent	4.1, 4.2	Covered provided that the documentation listed below in the comments column of this table is incorporated into the quality system documentation.
3.1 second paragraph 3rd indent	4.1, 5.1, 5.4, 5.5, 5.6	Covered
3.1 second paragraph 4th indent	4.1, 5.1, 5.4, 5.5, 5.6	Covered
3.1 second paragraph 5th indent	4.1, 4.2	Covered in part provided that quality management system includes the technical documentation relating to the applicable approved type(s) of medical device(s) Reference to the EC type-examination certificate is not covered
3.1 second paragraph 6th indent	7.2.3 c. 8.2.1, 8.3, 8.4, 8.5.1, 8.5.2	Covered in part. Annex 5 has specific expectations on a proactive post market surveillance system, updating of clinical data with post market surveillance information, reporting adverse events and field safety corrective actions
3.2 first paragraph	1.1	Covered provided that the legal requirements are examined, applied and verified, and the solutions adopted become part of the quality system in the meaning of the Directive.
3.2 second paragraph	4.1, 4.2	Covered
3.2 third paragraph (a)	4.2.1, 5.1, 5.3, 5.4.1	Covered
3.2 third paragraph (b) 1st indent	5.5.1, 5.5.2	Covered

Table ZA.2 — Relationship between Annex 5 of Directive 90/385/EEC (as amended) and the clauses of EN ISO 13485

Paragraph of Directive 90/385/EEC, Annex 5	Clause(s) of EN ISO 13485	Comments/Qualifying remarks
3.2 third paragraph (b) 2nd indent	4.1, 5.6, 7.1, 8.2.2, 8.3, 8.4, 8.5.2, 8.5.3	Covered provided that the methods and acceptance criteria chosen by the manufacturer ensure that the requirements of the Directive are fulfilled.
3.2 third paragraph (b) 3rd indent	1.2, 4.1, 4.2, 7.4, 8.5.1	Covered
3.2 third paragraph (c) 1st indent	4.2, 6.4, 7.1, 7.4, 7.5.1, 7.5.2	Covered provided that the quality management system documentation includes relevant documents and records in regards to sterilization and purchasing
3.2 third paragraph (c) 2nd indent	4.2, 7.5.3	Covered
3.2 third paragraph (d)	7.1,7.4.3,7.6, 8.2.4	Covered provided that the frequency at which tests are carried out is documented in the quality management system documentation.

WARNING — The preceding text and tables are specifically intended for organizations that need to comply with the European Directive 90/385/EEC in order to affix CE marking on their products and for other parties involved in that process. Other Directives might also be applicable and require a CE marking.

Annex ZB
(informative)

Relationship between this European Standard and the Conformity Assessment Requirements of EU Directive 93/42/EEC (as amended)

ZB.1 General

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means by which a manufacturer may demonstrate conformity, and by which the Notified Body may assess the manufacturer's conformity, with the requirements of Directive 93/42/EEC (as amended) on medical devices.

Within the limits of the scope of this standard (Clause 1 of EN ISO 13485:201X), compliance with the normative clauses of this standard according to the qualifying remarks presented in Tables ZB.1, ZB.2 and ZB.3 confers presumption of conformity with the requirements on a manufacturer's quality system[2)] as given in Annexes II, V and VI of that Directive and associated EFTA regulations, once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State. This Annex ZB explains to which requirements, under which conditions and to what extent presumption of conformity can be claimed.

The Conformity Assessment Annexes II, V and VI of the Directive include description of the regulatory process and activities undertaken by the Notified Body, which both are outside of the scope of EN ISO 13485 and therefore not covered by this standard. Furthermore, the requirements of the Directive refer to an application to a Notified Body, not to the requirement for a quality system as such. Accordingly, coverage of legal requirements can only be presumed to the extent listed in Tables ZB.1, ZB.2 and ZB.3 if the application to a Notified Body:

- contains the necessary quality system documentation;
- has been reviewed and approved by a Notified Body,

and the undertakings listed in the application are correctly executed by the manufacturer.

ZB.2 Relationship with Annex II of Directive 93/42/EEC (as amended)

Compliance with EN ISO 13485 does not provide a presumption of conformity with all the aspects of Annex II, as outlined in Table ZB.1. Therefore, a manufacturer or a Notified Body has to take additional provisions to ensure conformity, and claim or certify conformance, with Annex II of this Directive. The legal requirements must be examined, applied and verified one by one and the solutions adopted must become part of the quality system in the meaning of the Directive.

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2) This annex uses the term "quality system" as used in the Directive whereas EN ISO 13485 uses the term "quality management system" in accordance with ISO terminology.

Table ZB.1 — Relationship between Annex II of Directive 93/42/EEC (as amended) and the clauses of EN ISO 13485

Paragraph of Directive 93/42/EEC, Annex II	Clause(s) of EN ISO 13485	Comments/Qualifying remarks
3.1 first sentence		Not covered
3.1 second sentence 1st indent		Not covered
3.1 second sentence 2nd indent		Not covered
3.1 second sentence 3rd indent		Not covered
3.1 second sentence 4th indent	4.1, 4.2	Covered provided that the documentation listed below in the comments column of this table is incorporated into the quality system documentation.
3.1 second sentence 5th indent	4.1, 5.1, 5.4, 5.5, 5.6	Covered
3.1 second sentence 6th indent	4.1, 5.1, 5.4, 5.5, 5.6	Covered
3.1 second sentence 7th indent 3.1 7th indent (i) 3.1 7th indent (ii)	7.2.3 c. 8.2.1, 8.3, 8.4, 8.5.1, 8.5.2	Covered in part. Annex II has specific expectations on a proactive post market surveillance system, updating of clinical data with post market surveillance information, reporting adverse events and field safety corrective actions
3.2 first paragraph first sentence	1.1	Covered provided that the legal requirements are examined, applied and verified, and the solutions adopted become part of the quality system in the meaning of the Directive.
3.2 first paragraph second sentence	4.1, 4.2, 7.1	Covered
3.2 second paragraph	4.1, 4.2, 7	Covered provided that the documentation listed below in the comments column of this table is incorporated into the quality system documentation.
3.2 third paragraph (a)	4.2.1.1, 5.1, 5.3, 5.4.1	Covered
3.2 third paragraph (b)	4.2.2, 5.1	Covered
3.2 third paragraph (b) 1st indent	1.2, 4.2.2, 5.1, 5.5.1, 5.5.2	Covered

Table ZB.1 — Relationship between Annex II of Directive 93/42/EEC (as amended) and the clauses of EN ISO 13485

Paragraph of Directive 93/42/EEC, Annex II	Clause(s) of EN ISO 13485	Comments/Qualifying remarks
3.2 third paragraph (b) 2nd indent	4.1, 5.6, 7.1, 8.2.2, 8.3, 8.4, 8.5.2, 8.5.3	Covered provided that the methods and acceptance criteria chosen by the manufacturer ensure that the requirements of the Directive are fulfilled.
3.2 third paragraph (b) 3rd indent	1.2, 4.1, 4.2, 7.4, 8.5.1	Covered.
3.2 third paragraph (c)	7.1, 7.2, 7.3	Covered
3.2 third paragraph (c) 1st indent	4.2.1.2, 7.2, 7.3.2, 7.3.3	Covered
3.2 third paragraph (c) 2nd indent	4.2, 7.3.2, 7.3.3, 7.3.6, 7.3.8	Covered provided that the applicable quality management system documentation includes design specifications identifying standards which will be applied and a description of the solutions adopted to fulfil the essential requirements which apply when harmonized standards are not applied in full,
3.2 third paragraph (c) 3rd indent	7.3.1, 7.3.5, 7.3.6, 7.3.7, 7.3.8	Covered
3.2 third paragraph (c) 4th indent	7.3.2, 7.3.3, 7.3.5, 7.3.6	Covered
3.2 third paragraph (c) 5th indent	4.2.1.2	Covered provided that the quality management system documentation includes a statement indicating whether or not the medical device incorporates, as an integral part, a substance or a human blood derivative and the data on the tests conducted in this connection required to assess the safety, quality and usefulness of that substance or human blood derivative, taking account of the intended purpose of the medical device,.
3.2 third paragraph (c) 6th indent	4.2.1.2	Covered provided that the quality management system documentation includes a statement indicating whether or not the device is manufactured utilising tissues of animal origin as referred to in Commission Directive 2003/32/EC
3.2 third paragraph (c) 7th indent	4.1.3, 7.1, 7.3.2, 7.3.3, 7.3.5, 7.3.6	Not covered
3.2 third paragraph (c) 8th indent	7.3.5, 7.3.8	Covered provided that the quality management system records include the pre-clinical evaluation
3.2 third paragraph (c) 9th indent	7.3.6	Not covered. 7.3.6 does not include the details of Annex X
3.2 third paragraph (c) 10th indent	4.1, 4.2, 7	Covered provided that the quality management system documentation includes the label and, where

Table ZB.1 — Relationship between Annex II of Directive 93/42/EEC (as amended) and the clauses of EN ISO 13485

Paragraph of Directive 93/42/EEC, Annex II	Clause(s) of EN ISO 13485	Comments/Qualifying remarks
		appropriate, instructions for use..
3.2 (d)	4.2, 7.1, 7.5.1, 7.5.2, 7.6, 8.1, 8.2.3, 8.2.4	Covered
3.2 third paragraph (d) 1st indent, sterilization	4.1.1, 6.4, 7.5.1, 7.5.2	Covered
3.2 third paragraph (d) 1st indent, purchasing	4.1.1, 7.4	Covered
3.2 third paragraph (d) 1st indent,	4.2, 7.1	Covered provided that the quality management system documentation includes relevant documents and records in regards to sterilization and purchasing
3.2 third paragraph (d) 2nd indent	4.2, 7.5.3	Covered
3.2 third paragraph (e)	7.1, 7.4.3,7.6, 8.2.4	Covered provided that the frequency at which tests are carried out is documented in the quality management system documentation
6.1	4.2.3, 4.2.4	Not covered. The specific time periods in Directive are not specified.

ZB.3 Relationship with Annex V of Directive 93/42/EEC (as amended)

Compliance with EN ISO 13485 does not provide presumption of conformity with all the aspects of Annex V, as outlined in Table ZB.2. Therefore, a manufacturer or a Notified Body has to take additional provisions to ensure conformity, and claim or certify conformance, with Annex V of this Directive. The legal requirements must be examined, applied and verified one by one and the solutions adopted must become part of the quality system in the meaning of the Directive.

Table ZB.2 — Relationship between Annex V of Directive 93/42/EEC and the clauses of EN ISO 13485

Paragraph of Directive 93/42/EEC, Annex V	Clause(s) of EN ISO 13485	Comments/Qualifying remarks
3.1 first paragraph		Not covered
3.1 second paragraph 1st		Not covered

Table ZB.2 — Relationship between Annex V of Directive 93/42/EEC and the clauses of EN ISO 13485

Paragraph of Directive 93/42/EEC, Annex V	Clause(s) of EN ISO 13485	Comments/Qualifying remarks
indent		
3.1 second paragraph 2nd indent		Not covered
3.1 second paragraph 3rd indent		Not covered
3.1 second paragraph 4th indent	4.1, 4.2	Covered provided that the documentation listed below in the comments column of this table is incorporated into the quality system documentation..
3.1 second paragraph 5th indent	4.1, 5.1, 5.4, 5.5, 5.6	Covered
3.1 second paragraph 6th indent	4.1, 5.1, 5.4, 5.5, 5.6	Covered
3.1 second paragraph 7th indent	4.1, 4.2	Covered in part provided that quality management system includes the technical documentation relating to the applicable approved type(s) of medical device(s) Reference to the EC type-examination certificate is not covered
3.1 second paragraph 8th indent 3.1 second paragraph 8th indent (i) 3.1 second paragraph 8th indent (ii)	7.2.3 c. 8.2.1, 8.3, 8.4, 8.5.1, 8.5.2	Covered in part. Annex II has specific expectations on a proactive post market surveillance system, updating of clinical data with post market surveillance information, reporting adverse events and field safety corrective actions
3.2 first paragraph	1.1	Covered provided that the legal requirements are examined, applied and verified, and the solutions adopted become part of the quality system in the meaning of the Directive.
3.2 second paragraph	4.1, 4.2	Covered
3.2 third paragraph (a)	4.2.1, 5.1, 5.3, 5.4.1	Covered
3.2 third paragraph (b)	4.2.2	Covered

Table ZB.2 — Relationship between Annex V of Directive 93/42/EEC and the clauses of EN ISO 13485

Paragraph of Directive 93/42/EEC, Annex V	Clause(s) of EN ISO 13485	Comments/Qualifying remarks
3.2 third paragraph (b) 1st indent	5.1, 5.5.1, 5.5.2	Covered
3.2 third paragraph (b) 2nd indent	4.1, 5.6, 7.1, 8.2.2, 8.3, 8.4, 8.5.2, 8.5.3	Covered provided that the methods and acceptance criteria chosen by the manufacturer ensure that the requirements of the Directive are fulfilled.
3.2 third paragraph (b) 3rd indent	1.2, 4.1, 4.2, 7.4, 8.5.1	Covered.
3.2 third paragraph (c) 1st indent	4.2, 6.4, 7.1, 7.4, 7.5.1, 7.5.2	Covered provided that the quality management system documentation includes relevant documents and records in regards to sterilization and purchasing
3.2 third paragraph (c) 2nd indent	4.2, 7.5.3	Covered
3.2 third paragraph (d)	7.1, 7.4.3,7.6, 8.2.4	Covered provided that the frequency at which tests are carried out is documented in the quality management system documentation.

ZB.4 Relationship with Annex VI of Directive 93/42/EEC (as amended)

Compliance with EN ISO 13485 does not provide presumption of conformity with all the aspects of Annex VI, as outlined in Table ZB.3. Therefore, a manufacturer or a Notified Body has to take additional provisions to ensure conformity, and claim or certify conformance, with Annex VI of this Directive. The legal requirements must be examined, applied and verified one by one and the solutions adopted must become part of the quality system in the meaning of the Directive.

Table ZB.3 — Relationship between Annex VI of Directive 93/42/EEC (as amended) and the clauses of EN ISO 13485

Paragraph of Directive 93/42/EEC, Annex VI	Clause(s) of EN ISO 13485	Comments/Qualifying remarks
3.1 first paragraph		Not covered
3.1 second paragraph 1st indent		Not covered
3.1 second paragraph 2nd indent		Not covered
3.1 second paragraph 3rd indent		Not covered
3.1 second paragraph 4th indent	4.1, 4.2	Covered provided that the documentation listed below in the comments column of this table is incorporated into the quality system documentation.
3.1 second paragraph 5th indent	4.1, 5.4, 5.5, 5.6	Covered
3.1 second paragraph 6th indent	4.1, 5.4, 5.5, 5.6	Covered
3.1 second paragraph 7th indent	4.1, 4.2	Covered in part provided that quality management system includes the technical documentation relating to the applicable approved type(s) of medical device(s) . Reference to the EC type-examination certificate is not covered
3.1 second paragraph 8th indent 3.1 second paragraph 8th indent (i)	7.2.3 c. 8.2.1, 8.3, 8.4, 8.5.1, 8.5.2	Covered in part Annex VI has specific expectations on a proactive post market surveillance system, updating of clinical data with post market surveillance information, reporting adverse events and field safety corrective actions

Table ZB.3 — Relationship between Annex VI of Directive 93/42/EEC (as amended) and the clauses of EN ISO 13485

Paragraph of Directive 93/42/EEC, Annex VI	Clause(s) of EN ISO 13485	Comments/Qualifying remarks
3.1 second paragraph 8th indent (ii)		
3.2 first sentence		Not covered
3.2 second and third sentences	4.1, 4.2	Covered
3.2 second paragraph 1st indent	4.2.1, 5.1, 5.3, 5.4.1	Covered
3.2 second paragraph 2nd indent	7.1, 7.4.3,7.6, 8.2.4	Covered provided that the frequency at which tests are carried out is documented in the quality management system documentation..
3.2 second paragraph 3rd indent	4.1, 5.6, 7.1, 8.2.2, 8.3, 8.4, 8.5.2, 8.5.3	Covered provided that the methods and acceptance criteria chosen by the manufacturer ensure that the requirements of the Directive are fulfilled.
3.2 second paragraph 4th indent	4.1, 4.2, 6.1	Covered
3.2 second paragraph 5th indent	1.2, 4.1, 4.2, 7.4, 8.5.1	Covered.
3.2 third paragraph		Not covered

WARNING — The preceding text and tables are specifically intended for organizations that need to comply with the European Directive 93/42/EEC in order to affix CE marking on their products and for other parties involved in that process. Other Directives might also be applicable and require a CE marking.

Annex ZC
(informative)

Relationship between this European Standard and the Conformity Assessment Requirements of EU Directive 98/79/EC

ZC.1 General

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means by which a manufacturer may demonstrate conformity, and by which the Notified Body may assess the manufacturer's conformity, with the requirements of Directive 98/79/EC on *in vitro* diagnostic medical devices.

Within the limits of the scope of this standard (Clause 1 of EN ISO 13485:201X), compliance with the normative clauses of this standard according to the qualifying remarks presented in Tables ZC.1, ZC.2 and ZC.3 confers presumption of conformity with requirements on a manufacturer's quality system[3)] as given in Annexes III, IV and VII of that Directive and associated EFTA regulations, once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State. This Annex ZC explains to which requirements, under which conditions and to what extent presumption of conformity can be claimed.

The Conformity Assessment Annexes III, IV and VII of the Directive include description of the regulatory process and activities undertaken by the Notified Body, which both are outside of the scope of EN ISO 13485 and therefore not covered by this standard. Furthermore, the requirements of the Directive refer to an application to a Notified Body, not to the requirement for a quality system as such. Accordingly, coverage of legal requirements can only be presumed to the extent listed in Tables ZC.1, ZC.2 and ZC.3 if the application to a Notified Body:

- contains the necessary quality system documentation;
- has been reviewed and approved by a Notified Body,

and the undertakings listed in the application are correctly executed by the manufacturer.

ZC.2 Relationship with Annex III of Directive 98/79/EC

Compliance with EN ISO 13485 does not provide a presumption of conformity with all the aspects of Annex III, as outlined in Table ZC.1. Therefore, a manufacturer or a Notified Body has to take additional provisions to ensure conformity, and claim or certify conformance, with Annex III of this Directive. The legal requirements must be examined, applied and verified one by one and the solutions adopted must become part of the quality system in the meaning of the Directive.

3) This annex uses the term "quality system" as used in the Directive whereas EN ISO 13485 uses the term "quality management system" in accordance with ISO terminology.

Table ZC.1 — Relationship between Annex III of Directive 98/79/EC and the clauses of EN ISO 13485

Paragraph of Directive 98/79/EC, Annex III	Clause(s) of EN ISO 13485	Comments/Qualifying remarks
3 first sentence		Not covered
3 1st indent	4.2.1.2, 7.2, 7.3.2, 7.3.3	Covered
3 2nd indent	4.1, 4.2	Covered provided that the documentation listed below in the comments column of this table is incorporated into the quality system documentation.
3 3rd indent	4.2, 7.1, 7.3, 7.5	Covered provided that the quality management system documentation includes design information, including the determination of the characteristics of the basic materials, characteristics and limitation of the performance of the medical devices, methods of manufacture and, in the case of instruments, design drawings, diagrams of components, sub-assemblies, circuits and the like
3 4th indent		Covered provided that, in the case of devices containing tissues of human origin or substances derived from such tissue, the quality management system documentation information on the origin of such material and on the conditions in which it was collected,
3 5th indent	4.1, 4.2	Covered provided that the quality management system documentation includes the descriptions and explanations necessary to understand the characteristics of the medical device drawings and diagrams and the operation of the product,
3 6th indent	4.2, 7.3.2, 7.3.3, 7.3.6, 7.3.8	Covered provided that the quality management system documentation includes the results of the risk analysis and, where appropriate, a list of the standards applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the Directive if harmonized standards have not been applied in full,
3 7th indent	6.4, 7.5.1.2, 7.5.1.3, 7.5.2	Covered
3 8th indent	4.2.1, 7.1.8.1, 7.3.3, 7.3.4, 7.3.5, 7.3.6, 7.4.3, 8.2.3, 8.2.4	Covered
3 9th indent	7.3.2, 7.3.3, 7.3.5, 7.3.6	Covered
3 10th indent	4.2.4, 8.2.4	Covered

Table ZC.1 — Relationship between Annex III of Directive 98/79/EC and the clauses of EN ISO 13485

Paragraph of Directive 98/79/EC, Annex III	Clause(s) of EN ISO 13485	Comments/Qualifying remarks
3 11th indent		Covered providing the quality management system documentation includes data from studies in a clinical or other appropriate environment or result from relevant biographical references showing adequate performance evaluation data showing the performances claimed by the manufacturer and supported by a reference measurement system (when available), with information on the reference methods, the reference materials, the known reference values, the accuracy and measurement units used.
3 12th indent	4.2.1.2	Covered providing the quality management system documentation includes the labels and instructions for use,
3 13th indent	4.2	Covered providing the quality management system reords includes the results of stability studies.
4 paragraph 1	1, 4-8	Covered
4 paragraph 2 1st indent	1.2, 4.2.2, 5.1, 5.5.1, 5.5.2	Covered
4 paragraph 2nd indent	4, 6, 7, 8	Covered
4 paragraph 3rd indent	4.1, 5.6, 7.1, 8.2.2, 8.3, 8.4, 8.5.2, 8.5.3	Covered provided that the methods and acceptance criteria chosen by the manufacturer ensure that the requirements of the Directive are fulfilled.
5	7.2.3 c. 8.2.1, 8.3, 8.4, 8.5.1, 8.5.2	Covered in part. Annex III has specific expectations on a proactive post market surveillance system, updating of clinical data with post market surveillance information, reporting adverse events and field safety corrective actions

ZC.3 Relationship with Annex IV of Directive 98/79/EC

Compliance with EN ISO 13485 does not provide presumption of conformity with all the aspects of Annex IV, as outlined in Table ZC.2. Therefore, a manufacturer or a Notified Body has to take additional provisions to ensure conformity, and claim or certify conformance, with Annex IV of this Directive. The legal requirements must be examined, applied and verified one by one and the solutions adopted must become part of the quality system in the meaning of the Directive.

Table ZC.2 — Relationship between Annex IV of Directive 98/79/EC and the clauses of EN ISO 13485

Paragraph of Directive 98/79/EC, Annex IV	Clause(s) of EN ISO 13485	Comments/Qualifying remarks
3.1 first paragraph		Not covered
3.1 second paragraph 1st indent		Covered providing the quality management system documentation includes the name and address of the manufacturer and any additional manufacturing site covered by the quality management system,
3.1 second paragraph 2nd indent	4.1, 4.2	Covered provided that the quality management system documentation includes adequate information on the medical device or medical device category covered by the quality management system.
3.1 second paragraph 3rd indent		Not covered
3.1 second paragraph 4th indent	4.1, 4.2	Covered provided that the documentation listed below in the comments column of this table is incorporated into the quality system documentation.
3.1 second paragraph 5th indent	4.1, 5.1, 5.4, 5.5, 5.6	Covered
3.1 second paragraph 6th indent	4.1, 5.1, 5.4, 5.5, 5.6	Covered
3.1 second paragraph 7th indent	7.2.3 c. 8.2.1, 8.3, 8.4, 8.5.1, 8.5.2	Covered in part. Annex III has specific expectations on a proactive post market surveillance system, updating of clinical data with post market surveillance information, reporting adverse events and field safety corrective actions
3.2 first sentence		Not covered
3.2 second sentence	4.1, 4.2	Covered
3.2 second paragraph (a)	4.2.1, 5.1, 5.3, 5.4.1	Covered
3.2 second paragraph (b)	4.2.2	Covered
3.2 second paragraph (b) 1st indent	5.5.1, 5.5.2	Covered
3.2 second paragraph (b) 2nd indent	5.6, 8.2.2, 8.3, 8.5.2	Covered
3.2 second paragraph (c) 1st indent	1.1	Covered provided that the legal requirements are examined, applied and verified, and the solutions adopted become part of the quality system in the meaning of the Directive.
3.2 second paragraph (c) 2nd indent reference to Annex III	4.2, 7.1, 7.3, 7.5	Covered provided that the quality management system documentation includes design information, including the

Table ZC.2 — Relationship between Annex IV of Directive 98/79/EC and the clauses of EN ISO 13485

Paragraph of Directive 98/79/EC, Annex IV	Clause(s) of EN ISO 13485	Comments/Qualifying remarks
– section 3 3rd indent		determination of the characteristics of the basic materials, characteristics and limitation of the performance of the medical devices, methods of manufacture and, in the case of instruments, design drawings, diagrams of components, sub-assemblies, circuits and the like
3.2 second paragraph (c) 2nd indent reference to Annex III – section 3 4th indent	4.1, 4.2	Covered provided that, in the case of devices containing tissues of human origin or substances derived from such tissue, the quality management system documentation information on the origin of such material and on the conditions in which it was collected,
3.2 second paragraph (c) 2nd indent reference to Annex III – section 3 5th indent	4.1, 4.2	Covered provided that the quality management system documentation includes the descriptions and explanations necessary to understand the characteristics of the medical device drawings and diagrams and the operation of the product,
3.2 second paragraph (c) 2nd indent reference to Annex III – section 3 6th indent	4.2, 7.3.2, 7.3.3, 7.3.6, 7.3.8	Covered provided that the quality management system documentation includes the results of the risk analysis and, where appropriate, a list of the standards applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the Directive if harmonized standards have not been applied in full,
3.2 second paragraph (c) 2nd indent reference to Annex III – section 3 7th indent	6.4, 7.5.1.2, 7.5.1.3, 7.5.2	Covered
3.2 second paragraph (c) 2nd indent reference to Annex III – section 3 8th indent	4.2.1, 7.1.8.1, 7.3.3, 7.3.4, 7.3.5, 7.3.6, 7.4.3, 8.2.3, 8.2.4	Covered
3.2 second paragraph (c) 2nd indent reference to Annex III – section 3 9th indent	7.3.2, 7.3.3, 7.3.5, 7.3.6	Covered
3.2 second paragraph (c) 2nd indent reference to Annex III – section 3 10th indent	4.2.4, 8.2.4	Covered
3.2 second paragraph (c) 2nd indent reference to Annex III – section 3 11th indent	4.1, 4.2	Covered providing the quality management system documentation includes data from studies in a clinical or other appropriate environment or result from relevant biographical references showing adequate performance evaluation data showing the performances claimed by the manufacturer and supported by a reference measurement system (when available), with information on the reference methods, the reference materials, the known reference values, the accuracy and measurement units used
3.2 second paragraph (c) 2nd indent reference to Annex	4.2.1.2	Covered providing the quality management system documentation includes the labels and instructions for use

Table ZC.2 — Relationship between Annex IV of Directive 98/79/EC and the clauses of EN ISO 13485

Paragraph of Directive 98/79/EC, Annex IV	Clause(s) of EN ISO 13485	Comments/Qualifying remarks
III – section 3 12th indent		
3.2 second paragraph (c) 2nd indent reference to Annex III – section 3 13th indent	4.2	Covered providing the quality management system records includes the results of stability studies
3.2 second paragraph (d) 1st indent	6.4, 7.5.1, 7.5.2	Covered
3.2 second paragraph (d) 2nd indent	7.4	Covered
3.2 second paragraph (d) 3rd indent	7.5.1, 7.5.2, 7.4, 4.2	Covered
3.2 second paragraph (e)	4.2, 7.1, 7.6, 8.2.4	Covered provided that the frequency at which tests are carried out is documented in the quality management system documentation.

ZC.4 Relationship with Annex VII of Directive 98/79/EC

Compliance with EN ISO 13485 does not provide presumption of conformity with all the aspects of Annex VII, as outlined in Table ZC.3. Therefore, a manufacturer or a Notified Body has to take additional provisions to ensure conformity, and claim or certify conformance, with Annex VII of this Directive. The legal requirements must be examined, applied and verified one by one and the solutions adopted must become part of the quality system in the meaning of the Directive.

Table ZC.3 — Relationship between Annex VII of Directive 98/79/EC and the clauses of EN ISO 13485

Paragraph of Directive 98/79/EC, Annex VII	Clause(s) of EN ISO 13485	Comments/Qualifying remarks
3.1 first paragraph		Not covered
3.1 second paragraph 1st indent, reference to Annex IV, 3.1, 1st indent	4.1, 4.2	Covered providing the quality management system documentation includes the name and address of the manufacturer and any additional manufacturing site covered by the quality management system,
3.1 second paragraph	4.1, 4.2	Covered provided that the quality management system documentation includes adequate information on the

Table ZC.3 — Relationship between Annex VII of Directive 98/79/EC and the clauses of EN ISO 13485

Paragraph of Directive 98/79/EC, Annex VII	Clause(s) of EN ISO 13485	Comments/Qualifying remarks
1st indent, reference to Annex IV, 3.1, 2nd indent		medical device or medical device category covered by the quality management system
3.1 second paragraph 1st indent, reference to Annex IV, 3.1, 3rd indent		Not covered
3.1 second paragraph 1st indent, reference to Annex IV, 3.1, 4th indent	4.1, 4.2	Covered provided that the documentation listed below in the comments column of this table is incorporated into the quality system documentation.
3.1 second paragraph 1st indent, reference to Annex IV, 3.1, 5th indent	4.1, 5.1, 5.4, 5.5, 5.6	Covered
3.1 second paragraph 1st indent, reference to Annex IV, 3.1, 6th indent	4.1, 5.1, 5.4, 5.5, 5.6	Covered
3.1 second paragraph 1st indent, reference to Annex IV, 3.1, 7th indent	7.2.3 c. 8.2.1, 8.3, 8.4, 8.5.1, 8.5.2	Covered in part. Annex III has specific expectations on a proactive post market surveillance system, updating of clinical data with post market surveillance information, reporting adverse events and field safety corrective actions
3.1 second paragraph 2nd indent	4.1, 4.2	Covered in part provided that quality management system includes the technical documentation relating to the applicable approved type(s) of medical device(s) Reference to the EC type-examination certificate is not covered
3.2 first paragraph	1.1	Covered provided that the legal requirements are examined, applied and verified, and the solutions adopted become part of the quality system in the meaning of the Directive.
3.2 second paragraph	4.1, 4.2	Covered
3.2 third paragraph (a)	4.2.1, 5.1, 5.3, 5.4.1	Covered

Table ZC.3 — Relationship between Annex VII of Directive 98/79/EC and the clauses of EN ISO 13485

Paragraph of Directive 98/79/EC, Annex VII	Clause(s) of EN ISO 13485	Comments/Qualifying remarks
3.2 third paragraph (b)	4.2.2	Covered
3.2 third paragraph (b) 1st indent	5.5.1, 5.5.2	Covered
3.2 third paragraph (b) 2nd indent	5.6, 8.2.2, 8.3, 8.5.2	Covered
3.2 third paragraph (c) 1st indent	6.4, 7.5.1, 7.5.2	Covered
3.2 third paragraph (c) 2nd indent	7.4	Covered
3.2 third paragraph (c) 3rd indent	4.2, 7.5.1, 7.5.2, 7.4	Covered
3.2 third paragraph (d)	4.2, 7.1, 7.6, 8.2.4	Covered provided that the frequency at which tests are carried out is documented in the quality management system documentation.

WARNING — The preceding text and tables are specifically intended for organizations that need to comply with the European Directive 98/79/EC in order to affix CE marking on their products and for other parties involved in that process. Other Directives might also be applicable and require a CE marking.

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