ISO 13485:2016 Medical devices, quality management systems for regulatory purposes

Quality management for medical devices

71 requirements. This standard can be certified against by an accredited body. As of 07/2026.

ISO 13485 can be certified against by an accredited body. What gets certified is the organisation's quality management system, not a product. Important: the certificate is not a conformity assessment under MDR or IVDR, it does not lead to CE marking, and it replaces neither the Notified Body nor an FDA inspection. This list covers the standard, not the MDR. Anyone who conflates the two ends up holding a certificate and still may not place the device on the market. This list is a working aid for self-assessment, not a proof.

Company	Date	Prepared by

4 Quality Management System and Documentation 11

4.1-a Document

The quality management system is documented, maintained and kept effective. The role the organisation takes in the market, for example manufacturer, authorised representative, importer or distributor, is recorded in writing, together with the regulatory requirements that follow from that role.

What proves it: A short foundational document or a chapter of the manual that names the role held and lists the applicable regulatory frameworks per target market, with date and revision. A small operation keeps this to two pages: one table with target market, role, applicable framework, responsible person, and the date of the last review.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

4.1-b

The processes needed for the quality management system are identified, their sequence and interaction are described, and their application throughout the organisation is governed. The type and depth of control follow the risk that each process carries for the product and for user safety.

What proves it: A process map or process list showing interfaces, plus a short risk rating per process that explains why it is controlled tightly or loosely. For a small operation a single overview table is enough: process, owner, risk level, depth of control.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

4.1-c

Criteria and methods are defined for the processes so that effective operation and control are ensured. The required resources and information are available, the processes are monitored, measured and evaluated, and the actions needed to achieve the planned results are taken and recorded.

What proves it: Process descriptions or work instructions with defined metrics and acceptance criteria, together with the ongoing evaluations and the resulting actions with their implementation status. Without any apparatus a lean metrics list updated monthly is enough, plus a short record whenever a deviation occurs.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

4.1-d

Changes to processes of the quality management system are assessed before they are implemented, covering the effect on the system itself, on the products manufactured and on the applicable regulatory requirements. The assessment and the approval of the change are recorded so that they can be traced.

What proves it: Change requests or change records with fields for impact assessment, affected products, regulatory relevance, approval and date. A small operation keeps a single numbered change list in which every line carries the assessment and the signature of the approving person.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

4.1-e Document

Processes placed with external parties remain the responsibility of the organisation and stay under its control. The extent of that control follows the risk involved and the ability of the partner to meet the requirements. The arrangements with the partner are agreed in writing and set out the quality obligations of both sides.

What proves it: A written quality agreement per outsourced process covering specifications, release paths, the duty to notify changes, records and the right to audit, together with the evidence of ongoing monitoring such as supplier evaluation or incoming goods inspection. For small volumes a two page annex to the existing supply contract is enough.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

4.1-f Document

Software used within the quality management system is checked before first use and after every change to the application or to the software itself to confirm that it serves its intended purpose. The depth of that check follows the risk that a software malfunction would carry for product and user, and the results are recorded.

What proves it: A defined approach to software validation, a list of the applications in use with a risk rating, and per application a test plan with test cases, result, date and approval. For common tools such as a spreadsheet with inspection formulas or a stock program, documented test cases with a known expected result and a screenshot of the actual result are enough.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

4.2.1 Document

The documented information of the system covers the quality policy and the quality objectives, a manual, the procedures and records expressly required by the standard, the documents needed for the organisation to plan, operate and control its processes, and any further records demanded by the applicable regulatory requirements.

What proves it: A document matrix that maps each clause of the standard to the corresponding in-house document and additionally identifies the records that stem from the regulatory framework. A small operation keeps this matrix as one table with the columns clause, document, revision, storage location, owner.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

4.2.2 Document

A manual describes the quality management system. It states the scope, lists the clauses that are not applied and justifies that decision. It contains the defined procedures or refers to them and sets out how the processes of the system interact. The structure of the entire documentation is visible in it.

What proves it: The manual itself, with revision status, approval and a chapter that lists the non-applied clauses with a factual justification, for example because no sterile products are made or no installation is provided. A length of twenty to thirty pages is usual and sufficient for small operations.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

4.2.3 Document

For each product type and product family a dedicated file exists that gives access to the product related records or contains them. It evidences the general description of the product, the intended use, the labelling and the instructions for use, the product specifications, and the arrangements for manufacture, packaging, storage, handling and distribution. It also holds the provisions for measurement and monitoring and, where applicable, the requirements for installation and for servicing.

What proves it: The medical device file per product, kept as a binder or a directory with a cover sheet that lists each element with document number, revision and storage location: drawings and bills of material, manufacturing and inspection instructions, packaging and storage requirements, inspection plans with acceptance criteria, installation and service instructions. For small operations it is acceptable and practical to hold only references in the file, as long as each reference points unambiguously to the valid revision. Where a category does not apply, that is stated in the file with a short justification, so that a gap is not mistaken for an omission.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

4.2.4 **Documents are reviewed for adequacy and approved before issue, updated and re-approved when needed, and their revision status is visible. The valid revision is present where it is used, is legible and clearly identified, documents of external origin are likewise controlled, and obsolete revisions are protected against unintended use. At least one copy of each obsolete revision is retained for a defined period.** Document

What proves it: A defined approach to document control, a document list with revision status, approver and approval date, and an archive of the obsolete revisions marked as invalid. Without a system a folder Valid and a folder Archive with a lock note are enough; what counts is that nobody works from an outdated instruction by accident.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

4.2.5 **Records evidence that the requirements are met and that the system is effective. They stay legible, are clearly identified and retrievable, and information relating to the health of individuals is protected against unauthorised access. The retention period is defined and covers at least the lifetime of the product as determined by the organisation, counted from release but not less than two years, unless the regulatory requirements demand a longer period.** Document

What proves it: A defined approach to record control with a retention matrix per record type, plus the rules for access and data protection covering patient and user data, and evidence of data backup where records are held electronically. A small operation places the periods in one table: record, storage location, retention period, deletion or destruction, owner.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

5 Management Responsibility 11

5.1-1 **Top management demonstrates in a traceable way that it carries the quality management system: it makes clear across the organization that both customer requirements and the applicable regulatory requirements for the medical devices are binding, it has put the quality policy into force, initiated quality objectives, conducted the management reviews and provided the necessary resources.**

What proves it: Management release note on the policy and the objectives with date and signature, management review records, budget and staffing decisions for quality and regulatory affairs, internal announcements or staff communications in which management explicitly names customer and regulatory requirements. A small operation covers this with a one-page management resolution per year plus the record of the annual review; a separate commitment document is not needed.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

5.2-1 **Top management ensures that customer requirements and the applicable regulatory requirements are determined and actually met, and treats both as equally ranking inputs to the product and to the processes.**

What proves it: Overview of the target markets with the regulations and standards applicable to each product, requirement clarification in sales or in contract review, references from the requirements specification and the product specification to the concrete regulatory sources. A small operation keeps a table per product family with the columns market, regulation, reference, owner and review status.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

5.3-1 **A quality policy released by top management exists, is appropriate to the organization, contains the commitment to meet requirements and to maintain the effectiveness of the management system, provides the framework for the quality objectives, is communicated and understood within the organization, and is reviewed for continuing suitability at defined intervals.** Document

What proves it: The policy as its own controlled documented information with revision status, date and release, evidence of communication such as a notice board, intranet, briefing list or onboarding pack, and a management review record entry in which the policy was confirmed or changed. In a small operation half a page is enough, provided every employee can restate it in their own words.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

5.4.1-1 **Quality objectives are established for the relevant functions and levels, they are stated in measurable terms, are linked to the quality policy and include the objectives needed to meet the product requirements and the regulatory requirements.** Document

What proves it: Objective sheet or objective matrix per area with metric, baseline, target value, deadline and owner, together with the measured values from the current year. Typical metrics are the number of justified complaints per 1000 units, on-time closure of CAPA actions, defect rate at final inspection. A small operation manages with three to five objectives; what matters is that the data source is named for each one.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

5.4.2-1 **Planning of the management system is set up so that the requirements of clause 4.1 and the quality objectives are achieved, and when changes to the system are planned its integrity and its ability to function are maintained.**

What proves it: Quality plan or annual plan with actions, dates and responsibilities, plus change requests for system changes including an assessment of the impact on processes, documented information, approvals and training needs. A small operation handles this with a simple change form that is released by management and by the person responsible for quality before implementation.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

5.5.1-1 **Responsibilities and authorities are defined, documented and communicated within the organization, the interrelations between all personnel who manage, perform or verify work affecting quality are documented as well, and these personnel can carry out their tasks independently.** Document

What proves it: Organization chart including deputy arrangements, function or job descriptions with tasks, authorities and deputies, and a matrix assigning each process to an owner. It matters that release and verification authority does not sit with the same person who performs the work. A small operation records this on one page and has the assignment countersigned by the people concerned.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

5.5.2-1 **A member of management is appointed irrespective of other duties and holds documented responsibility for implementing and maintaining the management system, for reporting to management on its effectiveness and on any need for improvement, and for promoting awareness of the regulatory requirements and the customer requirements throughout the organization.** Document

What proves it: Written appointment with date, signature of management and acceptance by the appointed person, together with that person's task description and the reports to management, for example the management review input package. A small operation may combine this role with another function, but the appointment must exist as a standalone record and must not be buried in a general job description.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

5.5.3-1 **Management has defined how the effectiveness of the management system is communicated within the organization, and these communication channels are actually used.**

What proves it: Communication plan or a short section in the manual stating trigger, channel, audience and frequency, for example shift handover, monthly quality round, posting of the metrics, circular email after complaints. Meeting notes, attendance lists and photos or printouts of the metrics board serve as evidence. A small operation covers this with a recurring short meeting plus a note.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

5.6.1-1 **A documented procedure for management review exists, the review takes place at defined and justified intervals, it examines the continuing suitability, adequacy and effectiveness of the system including conformity with the regulatory requirements, and records of it are kept.** Document

What proves it: Procedure describing frequency, participants, sequence and template, plus the records of the reviews performed with date, participants and results. The frequency has to be justified; annually is common, and a shorter interval is appropriate when there are many changes or complaints. A small operation works with a fixed agenda template that doubles as the record.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

5.6.2-1 **The review draws on at least the following inputs: feedback from the market and complaints, reports to regulatory authorities, audit results, results of monitoring and measurement of processes and product, status of corrective and preventive actions, follow-up from previous reviews, changes affecting the system, recommendations for improvement, and new or revised regulatory requirements.**

What proves it: A template in which every input has its own line together with a reference to its data source: complaint log, reporting register, audit reports, metrics sheet, CAPA list, action tracking from the previous review, change log, improvement suggestions, overview of changes in law and standards. A small operation deliberately keeps the template short, but no line may be missing; an item with no occurrences is closed with the note none in the period.

◯ Open ◯ In progress ◯ Met ◯ Not applicable

Evidence / justification

5.6.3-1 **The review produces documented decisions and actions relating to improvement and maintenance of the management system and its processes, to product improvement with regard to customer and regulatory requirements, and to resource needs.**

What proves it: Action plan as an annex to the record, listing action, owner, due date, resource need and completion status, plus follow-up in the next review. The decisions must be traceable back to the inputs so that it is visible that the review had an effect. A small operation keeps a running action list in which open items stay visible until they are closed.

◯ Open ◯ In progress ◯ Met ◯ Not applicable

Evidence / justification

6 Resource Management: Provision of Resources, Human Resources, Infrastructure and Work Environment 5

6.1-1 **The resources needed to operate and maintain the quality management system are determined and are actually made available. This includes the resources needed to meet product requirements and the applicable regulatory requirements, meaning people and their working time, budget, premises, equipment and external support.**

What proves it: Resource plan or budget line for the QMS, allocated time shares for the QMS representative and the person responsible for regulatory compliance, investment and purchasing list for inspection and production equipment, contracts with external service providers such as a test laboratory or a sterilisation contractor. A small organisation demonstrates this with a one page overview: who works how many hours per month, what the annual budget is, which acquisitions are planned, plus top management approval and a minuted item from the management review.

◯ Open ◯ In progress ◯ Met ◯ Not applicable

Evidence / justification

6.2-1 **For activities that affect product quality, the necessary competence in terms of education, training, skills and experience is defined. The approach used to determine that competence, to achieve it through training or other actions, and to verify the effectiveness of those actions is described in a documented procedure. Personnel are aware of how their work matters for quality and for the safety of the products, and records of education, training, skills and experience are held for every individual.** Document

What proves it: Documented procedure for competence and training, competence matrix by activity and person, training plan and training records with date and signature, personnel file or competence folder holding diplomas and certificates. Effectiveness is not merely asserted but evidenced, for example by a workplace release after supervised on the job training, by a test batch, a knowledge check or a documented observation carried out by an experienced person. A small organisation keeps this as one table: person, activity, required competence, evidence, date of the effectiveness check, next refresher.

◯ Open ◯ In progress ◯ Met ◯ Not applicable

Evidence / justification

6.3-1 **The infrastructure needed to achieve conformity to product requirements is determined and provided: buildings and workspace, process equipment including its hardware and software, and supporting services such as transport, communication and utilities. Maintenance requirements are documented, including their frequency, where maintenance can affect product quality. It is also defined how product is prevented from being adversely affected by equipment or by the environment, and the maintenance actually performed is recorded.** Document

What proves it: Asset and equipment list with location and purpose, maintenance schedule with intervals and responsible persons, maintenance and repair records, release of the equipment back into use after maintenance. For software that forms part of the process equipment, the version level and the settings belong in the record. A small organisation keeps one equipment sheet per machine showing the interval, the last and the next maintenance and the work carried out. The intervals are justified, for instance from manufacturer instructions or from own experience, and are reviewed after breakdowns.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

6.4-1 **The work environment conditions needed for the product to meet its requirements are documented, for example cleanliness, order, temperature, humidity, lighting or electrostatic charge. Where personnel can affect product quality through contact with the product or with the environment, the requirements for the health, cleanliness and clothing of personnel are defined, and persons working under special environmental conditions are qualified for that work or are supervised by a qualified person.** Document

What proves it: Documented work environment requirements per area, hygiene and clothing rules covering protective clothing, gloves, jewellery and reporting sick with an infection, cleaning schedule with sign off, records of monitored environmental parameters such as temperature and humidity. A small organisation solves this with a notice in each room stating the applicable limits and rules, a cleaning schedule to tick off, and a data logger whose values are read out and filed at regular intervals. The instruction of personnel in these rules is documented with a date.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

6.4-2 **Arrangements for the control of contaminated or potentially contaminated product are documented and implemented so that contamination of the work environment, of personnel or of other product is prevented. For sterile medical devices, the requirements for the control of contamination with microorganisms and particulate matter are documented in addition, and the required cleanliness is maintained during assembly and packaging.** Document

What proves it: Documented arrangement for contamination control, identification and segregation of contaminated product, cleaning and disinfection instructions stating agent, concentration and contact time. For sterile product in addition: defined limits for bioburden and particulate matter, environmental monitoring records, evidence for the cleanroom or clean area, airlock rules and gowning requirements. A small organisation fences off a clean area with clear access rules, records cleaning and measured values on a form sheet and has microbiological testing carried out externally. Handling of product returned from the field belongs here as well, for example a quarantine zone with its own identification.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

7 Product realization: planning, customer requirements, design and development, purchasing, production and monitoring equip

7.1-1 **Realization is planned for each product or product family and the outcome of that planning exists as documented information. The plan names the quality objectives and product requirements, the processes and resources needed, the acceptance criteria, and the activities for verification, validation, monitoring, measurement, handling, storage, distribution and traceability, together with the records these activities produce. It fits the other processes of the management system.** Document

What proves it: A realization plan or quality plan per product family, usually a table with the columns process step, governing document, characteristic checked, acceptance criterion, monitoring equipment, resulting record. A small operation writes two pages that point to the existing work and inspection instructions instead of repeating their content, carrying a date, a revision status and top management release.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

7.1-2 **Risk management is described as a process, covers the entire product life cycle and is actually applied during product realization. The records it produces are maintained and updated whenever new knowledge arrives from production, feedback, complaints, servicing or the market.** Document

What proves it: A risk management procedure, a risk management plan and a risk management file per product with a hazard list, risk analysis, controls, evidence of effectiveness and an evaluation of residual risk. The methodology of ISO 14971 is the usual route. A small operation keeps the file as one versioned table per product; on every complaint and every change the affected row is reviewed, dated and signed off.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

7.2-1 **Before any commitment is made to the customer, all product requirements are determined: those stated by the customer, those necessary for the intended use even when not stated, the regulatory requirements of the target markets, the requirements for user training or instruction, and any requirements the organization sets for itself.**

What proves it: A requirements list or specification per product that the quote and the order confirmation refer to, plus an overview of the target markets with the applicable approval, language and labelling obligations. A small operation keeps one table per product with the columns requirement, source, target market, met by, and updates it whenever a new market is released.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

7.2-2 **Product requirements are reviewed before the order is accepted: they are unambiguous, differences between enquiry, quote and order are resolved, regulatory requirements are covered, and the organization is able to meet the requirements. The result of the review and the resulting actions are recorded. If the order changes, the review is repeated and the affected areas receive the amended information.**

What proves it: An order review with date, reviewer and release, for example as a signed review block on the order confirmation covering feasibility, regulatory status, labelling, delivery date and price. Alongside it, the change notifications to production, purchasing and the person responsible for regulatory matters, traceable through the distribution list or the order log.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

7.2-3 **The channels for communicating with customers and with authorities are defined and documented. They cover product information, enquiries and order changes, feedback and complaints, and safety information and advisory notices to users.** Document

What proves it: A communication matrix or procedure stating trigger, channel, responsibility and deadline; a template for an advisory notice to customers; a contact list of the competent authorities in the target markets. Outgoing post, traceable email threads and the complaint file serve as evidence. A small operation writes a single page saying who informs whom within which deadline in an emergency, and names a deputy.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

7.3-1 **Design and development runs according to a documented procedure, and a documented plan exists for every project. It defines the stages, the reviews, verifications, validations and the transfer to production, the responsibilities and authorities, the resources needed, and the methods that ensure traceability from the inputs to the outputs. The plan is updated as work progresses.** Document

What proves it: A design and development procedure plus a project plan with a stage overview, dates, owners and release points, together with a traceability matrix linking every input to its output, the verification evidence and the entry in the risk file. A small operation keeps plan and matrix as one versioned table, every update carrying a date and initials.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

7.3-2 **The design inputs are recorded and cover function, performance, usability and safety for the intended purpose, the regulatory requirements, the outputs of risk management, the applicable standards with their issue status, and experience from comparable earlier products. The inputs are complete, free of contradiction, verifiable as worded, and released before further work starts.**

What proves it: An approved input list or specification with date and signature, each line worded so it can be checked, that is with a target value and a tolerance rather than with aspirational wording. Contradictions and open points sit in a clarification list that is closed before the next stage begins. The reference to the risk analysis and to the standards applied is part of the list.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

7.3-3 **The design outputs are in a form that allows comparison against the inputs. They provide the information needed for purchasing, production and servicing, state the acceptance criteria, and describe the characteristics essential for safe and intended use. They are reviewed and approved before release, and the approval is recorded.**

What proves it: Approved drawings, bills of material, specifications, inspection instructions, labelling and instructions-for-use text, packaging requirements, each with an approval mark and an issue status. The acceptance criteria appear where the check is performed, not only in the design folder. The outputs are consolidated in the medical device file per 4.2.3 or clearly referenced from it.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

7.3-4 **Systematic design reviews take place at the points fixed in the plan. Representatives of the functions concerned take part, plus further specialists where needed. The review addresses whether the outputs meet the requirements, which problems remain open, and which actions will close them. The design state reviewed, the participants, the date and the result are recorded.**

What proves it: Minutes per review with an attendance list, the version number examined, the open points with an owner and a date, and the decision on whether the next stage may start. A small operation uses one unchanging single-page template so no point is forgotten, and invites production and quality alongside design.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

7.3-5 Document **Verification is planned and documented in advance: methods, acceptance criteria and, where sampling is used, the rationale for the sample size. Verification shows that the outputs meet the inputs. If the product is intended to be used in connection with another product, verification includes that connection. The evidence is recorded.**

What proves it: A verification plan and test reports naming the item tested and its version, the equipment used, the date, the tester and the result against the acceptance criterion. Where sampling is used, a short written rationale for the size, derived from the risk of the characteristic. Deviations are closed with an action and a documented recheck, not passed over in silence.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

7.3-6 Document **Validation is planned and documented and is carried out on product representative of series production. It demonstrates that the product meets the requirements for the intended use and the intended user, includes the clinical evaluation or performance evaluation where required, and is complete before the product is released for use by the customer.**

What proves it: A validation plan and validation report stating which batch or build the samples came from and why they are representative, plus the usability evidence gathered with users from the target group and, where required, the clinical or performance evaluation. The batch numbers of the validation samples are recorded so traceability stays unbroken.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

7.3-7 **The transfer of design outputs into production follows a described approach. Before series release it is checked and recorded that the outputs are suitable as production specifications and that the process yields product with the required characteristics.**

What proves it: A transfer checklist covering the release of work and inspection instructions, tooling, fixtures, monitoring equipment and the training of production staff, plus the evidence from a first production run or a process capability study. A small operation demonstrates the transfer through a first article inspection signed off jointly by production and quality.

◯ Open ◯ In progress ◯ Met ◯ Not applicable

Evidence / justification

7.3-8 **Design changes are reviewed, verified, validated where necessary and approved before they are implemented. The review explicitly addresses what the change means for function, performance, usability, safety, the risk file, regulatory requirements, and for product already made, in stock and in the field. The review and its result are recorded.**

What proves it: A change request with description, rationale and an impact assessment covering the risk file, labelling, approval status, stock on hand and field population, plus approval with date, implementation date and evidence of effectiveness. A running change register per product is enough, but it must be complete: every number is either implemented or rejected with a reason.

◯ Open ◯ In progress ◯ Met ◯ Not applicable

Evidence / justification

7.3-9 **A design and development file exists for each product or product family. It bundles or clearly references the design evidence, the changes and the link to the applicable requirements, so that fulfilment of the requirements remains traceable.** Document

What proves it: A file index per product listing document, version, date and location, covering at least plan, inputs, outputs, reviews, verification, validation, transfer and changes. The file sits close to the medical device file per 4.2.3. Duplicate upkeep is avoided by referencing rather than copying. A cover sheet with references is acceptable as long as the references hold.

◯ Open ◯ In progress ◯ Met ◯ Not applicable

Evidence / justification

7.4-1 **Purchasing follows a documented procedure that ensures purchased product conforms to the stated requirements. Suppliers are selected and evaluated against defined criteria, graded by their influence on the product and by the associated risk. Their performance is monitored and re-evaluated at defined intervals. Actions proportionate to the risk are defined for the case where requirements are not met. The evaluations are recorded.** Document

What proves it: A supplier procedure, a supplier list with approval status, an evaluation sheet with criteria and risk grading, figures on delivery reliability and quality, and minutes of the re-evaluation with a date. A small operation manages with one table: supplier, scope of supply, risk class, last evaluation, status, next evaluation. What matters is that blocked suppliers are visible to purchasing.

◯ Open ◯ In progress ◯ Met ◯ Not applicable

Evidence / justification

7.4-2 **Purchasing information describes the product to be purchased unambiguously and states, where applicable, specifications, requirements for inspection and acceptance, requirements for the qualification of the supplier's personnel and for the supplier's quality management system. It is agreed with the supplier in writing that changes to the purchased product are notified before they are implemented. The purchasing information is recorded to an extent that supports traceability.**

What proves it: A purchase order referring to a drawing or specification including its issue status, a quality assurance agreement or framework contract carrying the duty to notify changes, and an archive of orders. For catalogue items an unambiguous part number with a revision status is enough. A small operation puts the notification duty as a fixed clause in its purchasing terms and has the supplier confirm it in writing.

◯ Open ◯ In progress ◯ Met ◯ Not applicable

Evidence / justification

7.4-3 **Purchased product is verified before use. The extent of the check follows the outcome of the supplier evaluation and the risk of the part. When a change at the supplier becomes known, its effect on the product is assessed before the part is used further. Where verification takes place at the supplier's premises, the scope and criteria are agreed beforehand. The evidence is recorded.**

What proves it: An incoming inspection plan with an inspection extent graded by risk class, inspection records with lot, quantity, characteristic and result, and, where release is based on certificates, a comparison of the mill or works certificate against the specification. Supplier change notifications feed into an assessment that decides in documented form whether the part stays in use. Verification at the supplier is stated with its scope on the order.

◯ Open ◯ In progress ◯ Met ◯ Not applicable

Evidence / justification

7.5-1 **Production and service provision run under controlled conditions: documented procedures and work instructions, suitable equipment, defined process parameters and product characteristics, monitoring and measurement, and controlled release, delivery and post-delivery activities. For every batch or lot the quantity produced and the quantity released are recorded, the batch is uniquely identified, and the labels and instructions for use applied can be attributed to it.** Document

What proves it: A manufacturing instruction per product and a batch travelling record with batch number, quantities, components used including their batches, process parameters, inspection results, label and instructions-for-use version, and the signature releasing the batch. A small operation runs the travelling record as one form that moves with the lot through production and afterwards becomes the batch file.

◯ Open ◯ In progress ◯ Met ◯ Not applicable

Evidence / justification

7.5-2 **For product that is cleaned before sterilization or before use, that is supplied non-sterile and processed by the user, or from which process agents must be removed, the requirements for cleanliness and for preventing contamination are documented and implemented in the process.** Document

What proves it: A cleaning instruction stating agent, concentration, time, temperature and drying, release criteria for cleanliness, evidence on residues of process agents such as cutting fluid or release agent, and rules for gloves, clothing and packaging at final assembly. A small operation shows effectiveness through a one-off cleaning validation and afterwards through the documented adherence to the defined parameters.

◯ Open ◯ In progress ◯ Met ◯ Not applicable

Evidence / justification

7.5-3 **Where the product is installed, the installation requirements and the criteria for acceptance testing are documented and made available to the customer or to the appointed service provider. The installation performed and the acceptance test are recorded, including when a third party carries them out. Where installation does not apply to the product, that is recorded with a justification.** Document

What proves it: An installation instruction with an acceptance record signed by the installer and the customer, plus a rule stating within which period service partners return the records, and their filing in the product file. A small operation uses a two-page form: page one the steps to tick off, page two the measured values against target values with a signature.

◯ Open ◯ In progress ◯ Met ◯ Not applicable

Evidence / justification

7.5-4 **Where maintenance or servicing forms part of the scope of supply, documented procedures, reference material and requirements for the necessary measurements exist for it. Servicing records are analysed to recognize whether a case is to be handled as a complaint and to generate input for improvement.** Document

What proves it: A servicing instruction, a spare part and tool list, and service reports with unit number, fault picture, cause, action, parts used and date. Alongside them a regular analysis that makes clusters visible and documents in a traceable way the handover into complaint handling per 8.2.2. A small operation analyses the reports quarterly in a table by fault picture and records the decision.

◯ Open ◯ In progress ◯ Met ◯ Not applicable

Evidence / justification

7.5-5 **Sterilization processes and sterile barrier systems are validated according to documented procedures, before first use and again after changes to product, packaging or process. For every sterilization batch the process parameters are recorded, and the record can be unambiguously attributed to the corresponding production batch.** Document

What proves it: Validation reports for sterilization and for the packaging, that is seal integrity, seal strength and ageing, release of the process parameters, batch records with temperature, pressure, time or dose, biological indicators or dosimeters, and a release mark. With contract sterilization the service provider supplies the batch records; the organization files them with the production batch and checks them against the approved parameters before releasing.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

7.5-6 **Processes whose output cannot be fully checked by subsequent monitoring or measurement are validated according to a documented procedure. Defined are the criteria for review and approval, the qualification of the equipment, the qualification of personnel, the methods, the records and the triggers for revalidation. Software used in production or in monitoring is validated on a risk basis before use and after changes.** Document

What proves it: A list of the processes requiring validation with a rationale, typically welding, bonding, injection moulding, cleaning and sealing, plus validation reports covering installation, operational and performance qualification, evidence of personnel qualification, and the defined triggers for revalidation such as a change of machine, material or parameter. For software a short report per application is enough: purpose, risk, test cases, result, approval, plus fresh evidence after every update.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

7.5-7 **Product is identified throughout realization according to a documented procedure, the inspection and release status is recognizable at all times, and returned product is marked as such and kept separate from released goods. Where regulatory requirements call for a unique device identifier, its assignment is governed.** Document

What proves it: An identification procedure, travelling cards, labels, marking of locations and areas, colour or physical separation of quarantined, inspected and released goods, and an intake log for returns with a quarantine marking. A small operation works with three permanently signed areas and one travelling card per lot. That withstands an audit and needs no software.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

7.5-8 **The extent of traceability is defined and described in a documented procedure. The procedure names the records that must be created so that a product can be traced from the materials and components used, through the production and inspection steps, to delivery, and equally in the reverse direction.** Document

What proves it: A traceability procedure stating the defined traceability depth per product class, batch marking of raw material and bought-in parts, the links held in the batch file, and a delivery note carrying the batch number. A convincing piece of evidence is a dated trial run: pick a batch number, resolve it in both directions, and record the time taken and the result.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

7.5-9 **For implantable product, records of components, materials and of the working environment conditions are additionally maintained, insofar as those conditions could cause the product to fail its specification. Shipping and distribution records are kept, and are available from distribution partners, such that every product delivered can be traced to the recipient.**

What proves it: A batch file with all component and material batches, records of the environmental conditions such as particle count, microbial count, temperature and humidity for the steps concerned, and a shipping list with product, serial or batch number, recipient and date. Distributors have given a written undertaking to keep these records and to make them available on request. Retention periods are defined and are observed.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

7.5-10 **Customer property placed with the organization, such as tooling, supplied components, samples or confidential and personal data, is identified, protected and safeguarded. Loss, damage or unsuitability is reported to the customer and recorded.**

What proves it: A register of supplied items with marking, condition and storage location, written notification to the customer with a date in case of damage, and a rule for handling customer documents and patient data including access restriction. A small operation marks customer goods with coloured tags and keeps a single-page list that is signed off on return.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

7.5-11 **Product characteristics are preserved through processing, storage, handling and shipping to the intended destination according to documented requirements. Governed are protection against damage, contamination, mix-up and ageing, special conditions such as temperature or humidity together with their monitoring, and the removal from use of product whose shelf life has expired.** Document

What proves it: Packaging and storage requirements, management of expiry dates on a first in, first out basis, records of storage conditions, release of the transport packaging through a shipping test, and a quarantine rule for expired goods. A small operation evidences the monitoring with a data logger in the store and a monthly visual check that is signed off.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

7.6-1 **The monitoring and measuring equipment needed to demonstrate product conformity is determined and controlled according to a documented procedure: calibrated or verified before use and at defined intervals against traceable standards, adjusted where necessary, clearly identified, and protected against unauthorized adjustment and against damage. Where a measuring device is found to be faulty, the validity of earlier measurement results is assessed and actions for the affected product are defined. Software used for monitoring and measurement is validated before use and after changes. The evidence is recorded.** Document

What proves it: An equipment register with calibration interval, due date and status, calibration certificates traceable to national standards, calibration marks on the device, records of the assessment made after a deviation including the decision on the batches checked since the last valid calibration, and validation evidence for inspection software and for spreadsheets that compute measurement results. A small operation keeps the register as a table and has calibration done externally. What decides the case is the reasoning back from the suspect device to the affected product.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

8 Monitoring, Analysis of Data and Improvement of the Quality Management System 15

8.1-1 **The methods used to monitor, measure and analyse product conformity, the effectiveness of the quality management system and adherence to applicable regulatory requirements are planned and defined, including where statistical techniques are applied and to what extent.**

What proves it: A monitoring and measurement plan with the columns subject, method, frequency, responsible person and analysis, plus a short rationale for the sampling plans or acceptance criteria, for example an AQL table or 100 percent inspection. A small operation keeps this on a single page and explains there why full inspection makes more sense than sampling for small lot sizes.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

8.2.1-1 **A defined procedure exists for gathering and analysing feedback from production and from the post-production phase. The resulting information feeds back as an input into risk management, into the monitoring of product requirements and into product realization.** Document

What proves it: A documented feedback procedure naming the sources such as user reports, service records, training returns, distributor information and published literature, together with the analysed feedback showing date, assessment and the affected product family. Evidence of the feedback loop is an updated risk management file in which the input is visibly evaluated. Small manufacturers keep a single collection list that is reviewed once per quarter alongside the risk file.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

8.2.2-1 **Complaints are handled, evaluated and investigated in a timely manner in line with a defined procedure. Where no investigation is carried out, the justification is recorded and approved by a designated function within the organization. For every complaint it is also assessed whether a reporting obligation arises and whether corrective action needs to be triggered.** Document

What proves it: A complaint handling procedure with time limits and responsibilities, plus one complaint file per case: date received, product with lot or serial number, description, investigation result or justified waiver with approval, reportability assessment and a reference to any corrective action raised. A small operation uses a numbered complaint form and a summary table showing the status of each case.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

8.2.3-1 **It is defined in which cases, to which authority, within which time limit and by whom events are reported that are notifiable under the applicable regulatory requirements. The reports that were submitted are recorded.** Document

What proves it: A regulatory reporting procedure with a decision aid that separates reportable from non-reportable events, plus copies of the submitted reports with acknowledgement of receipt, date and handler. A short overview of the target authorities and time limits per market supplied is useful so that nobody has to start searching when it matters.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

8.2.4-1 **Internal audits follow a planned programme that takes into account the importance of the processes, the results of earlier audits and changed conditions. Objective, criteria, scope and frequency are defined for each audit, auditors do not audit their own work, and the results are reported to the responsible management. Detected nonconformities are eliminated without undue delay and the effectiveness is followed up.** Document

What proves it: An annual audit programme, an audit plan per date, an audit report with findings and distribution list, a statement on auditor independence, and an action list with due dates and effectiveness checks. Small operations solve the independence question through a collegial swap with another area or an external auditor engaged by the hour.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

8.2.5-1 **The processes of the quality management system are monitored with suitable methods and, where appropriate, measured, so that it is visible whether they deliver the planned results. Where the planned results are not achieved, correction and corrective action follow.**

What proves it: A metrics sheet per process with target value and actual trend, for example scrap rate, on-time delivery, share of successful process validations, complaint turnaround time. Alongside this, evidence that a missed target triggered a response, for example minutes of the process review with the actions derived. A small operation manages with three to five metrics maintained monthly on one sheet.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

8.2.6-1 **The defined product characteristics are verified at the planned stages, and release for delivery only takes place once all planned steps are complete. The records demonstrate that the acceptance criteria were met and identify the person who granted the release. For implantable devices, the persons who performed the inspections are additionally recorded.** Document

What proves it: An inspection instruction with acceptance criteria per characteristic, a completed inspection or lot record with measured values, the signature or unique system identifier of the releasing person and, for implants, the initials of the inspecting persons. Where product is released in advance, the documented authorization is part of the file. Small manufacturers run this as a travelling record sheet that accompanies the lot from raw material to release.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

8.3.1-1 **Nonconforming product is identified, marked, segregated from further use, evaluated and dispositioned. Responsibilities and authorities for these steps are set out in a defined procedure, and the evaluation includes the question of whether an investigation of the cause and notification of external parties are needed.** Document

What proves it: A procedure for the control of nonconforming product, a quarantine area or a marked quarantine container, a hold flag in the system, and records covering the nature of the nonconformity, the evaluation, the disposition and its justification. A small operation works with red tags and a separate locked shelf whose contents are tracked in a quarantine list.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

8.3.2-1 **Where a nonconformity is detected before delivery, it is decided whether the product is scrapped, held, corrected or used under concession. A concession is granted only with a documented justification, only by a person authorized to do so, and only where the regulatory requirements continue to be met.** Document

What proves it: A disposition record per case stating the action chosen, a concession form with justification, a link to the risk assessment and the signature of the authorized person, plus the list of people permitted to grant concessions. A plain table with a running number, lot, quantity, reason and releasing person is sufficient as evidence.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

8.3.3-1 **Where a nonconformity is only detected after delivery or after use has started, actions are taken that are appropriate to the effects, including the issuing of an advisory notice to users or customers under a defined procedure. Issuing must be possible at short notice at any time, and the actions taken are recorded.** Document

What proves it: A procedure for advisory notices and recalls with trigger criteria, a text template, distribution logic and response tracking, plus the customer list per lot taken from traceability, the notices sent with date and recipients, and a response overview showing how many recipients reacted. A dry run of the notification using a real lot demonstrates that the route works.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

8.3.4-1 **Rework is carried out only under released instructions that have passed through the same review and approval route as the original work instruction. Before the instruction is released, it is assessed whether the rework may have an adverse effect on the product, and the rework performed is recorded.** Document

What proves it: A rework instruction with an approval record, an assessment of the possible effects with a link to the risk file, and a rework record per case with lot, extent, the person performing it and the re-inspection. What matters is the recorded borderline: from which point onward the product is no longer reworked but scrapped.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

8.4-1 **It is defined which data are collected and analysed in order to judge the suitability and effectiveness of the quality management system. The analysis covers at least feedback and complaints, product conformity, characteristics and trends of processes and products, supplier performance, and results from audits and service reports. Where the analysis shows that the system is not effective, this is used as an input for improvement.** Document

What proves it: A procedure for the analysis of data with sources, methods and analysis cycle, plus the analysis outputs themselves, for example a quarterly review with trends, a Pareto view of complaint reasons and a supplier evaluation. These outputs are at the same time input material for the management review. A small operation produces a two page analysis sheet once per quarter instead of a software driven reporting system.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

8.5.1-1 **Necessary changes to the quality management system are identified and implemented so that the system remains suitable and effective and the safety and performance of the products is maintained. The basis for this is the quality policy and quality objectives, audit results, post market observation of the product, the analysis of data, corrective and preventive actions, and the management review.**

What proves it: An improvement list or action board showing the origin of the idea, the responsible person, the due date and the status, linked to the decisions from the management review. Evidence is a change that can be traced without gaps from the data source through the decision to the implemented adjustment of a procedure.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

8.5.2-1 **A defined procedure exists for corrective action: nonconformities are evaluated, the causes determined, the need for action judged, the necessary actions planned and implemented without undue delay, and their effectiveness verified. Before implementation it is checked whether the action could adversely affect adherence to regulatory requirements or the safety and performance of the product. The investigation and its results are recorded.** Document

What proves it: A corrective action procedure and a CAPA file per case with problem description, root cause analysis, for example 5 Why or Ishikawa, an action plan with dates, an impact check on the regulatory approval and on the risk file, and evidence of effectiveness after a defined interval. A small operation runs CAPA as a numbered folder of forms with a summary table for open cases and deadlines.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification

8.5.3-1 **A defined procedure exists for preventive action, used to identify potential nonconformities and their causes, judge the need for action, plan and implement actions and verify their effectiveness. Here too it is assessed before implementation whether the action touches the regulatory requirements or the safety and performance of the product, and the investigation is recorded.** Document

What proves it: A preventive action procedure and records per case naming the source that was analysed, for example a trend from the analysis of data, findings from a similar product, a near miss in production or a signal from the market, plus an action plan and an effectiveness check. The difference from corrective action must be visible on the form: nothing has gone wrong yet, it is only emerging.

○ Open ○ In progress ○ Met ○ Not applicable

Evidence / justification