ISO 13485

Medical devices — Quality management systems — Requirements for regulatory purposes

Condensed Practical Reference & Field Checklists

Prepared for use by quality/regulatory and biomedical engineering staff at medical device manufacturers, refurbishers, importers, and distributors — covering the structure of a compliant quality management system (QMS) and practical, ready-to-use checklists.

Important note on scope and use: *This document is an original, independently written condensed overview and practical checklist tool. It summarizes, in the author's own words, the general structure and areas of concern covered by ISO 13485:2016 for quick field reference. It is* ***not a reproduction of the official standard text****, is not a substitute for it, and must not be used as the sole basis for certification audits, gap assessments, or regulatory submissions. For any formal certification, audit, or regulatory compliance work, the current officially licensed ISO 13485:2016 text (and applicable regional regulation, e.g. EU MDR 2017/745, US 21 CFR Part 820 / QMSR, or the destination country's medical device regulation) must be consulted directly.*

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1. About This Standard

ISO 13485 is the internationally recognized quality management system (QMS) standard specifically for organizations involved in the medical device life cycle — design, development, production, installation, servicing, and related activities such as distribution, importation, refurbishment, and sterilization services. Unlike the more general ISO 9001, ISO 13485 is built around regulatory compliance and risk management as core objectives rather than customer satisfaction alone, and is widely required or referenced by medical device regulators worldwide (including the EU MDR/IVDR framework and many national authorities across the Middle East, Asia, and Latin America).

1.1 Who needs it, and why it matters for refurbishment/export businesses

- Manufacturers of new medical devices seeking CE marking or other national regulatory approval typically must operate a certified QMS conforming to ISO 13485 (or an equivalent recognized scheme).
- Organizations that **refurbish, remanufacture, or service** medical equipment — particularly for export — increasingly need to demonstrate an ISO 13485-aligned QMS to be accepted as credible suppliers in regional markets, even where not strictly mandated by local law.
- Distributors and importers are frequently required by destination-country regulation to show that their supply chain (including any refurbishment step) sits under a controlled quality system.
- Holding or working toward ISO 13485 certification is commonly used as a market differentiator and trust signal when competing for institutional and cross-border tenders.

1.2 Core structure

ISO 13485 follows a process-based structure similar in shape to ISO 9001, organized into four main operational clause groups plus supporting requirements:

- **Clause 4 — Quality management system:** general QMS requirements, documentation structure, document and record control.
- **Clause 5 — Management responsibility:** top management commitment, quality policy, planning, responsibility/authority, management review.
- **Clause 6 — Resource management:** human resources/competence, infrastructure, work environment, contamination control.
- **Clause 7 — Product realization:** planning, customer/regulatory requirements, design and development controls, purchasing, production and service provision controls, identification and traceability, preservation, and control of monitoring/measuring equipment.
- **Clause 8 — Measurement, analysis and improvement:** feedback and complaint handling, internal audit, process/product monitoring, control of nonconforming product, corrective and preventive action (CAPA), and post-market surveillance / vigilance reporting.

2. Summary of Key Requirement Areas by Clause

The table below gives a condensed, plain-language overview of what each major clause addresses. Clause numbers are provided for orientation only; always refer to the licensed standard for exact wording and requirements.

Clause	Topic	What it broadly covers
4	QMS & documentation	Documented QMS scope and processes; a controlled quality manual; document control (approval, revision, distribution, obsolete-document control); record control (legible, retrievable, retained for at least the device lifetime or per regulation).
5	Management responsibility	Top management demonstrates commitment; establishes a quality policy and measurable quality objectives; defines roles/authorities; ensures a management representative function; conducts planned management review at defined intervals.
6	Resource management	Competence, training, and awareness of personnel affecting quality; suitable infrastructure (buildings, equipment, IT); controlled work environment, including contamination control relevant to the product (e.g. cleanliness for refurbished/sterile-adjacent devices).
7.1–7.2	Planning & customer requirements	Quality planning for realization processes; review of customer and applicable regulatory requirements before accepting an order or contract; customer communication, including complaint-handling input.
7.3	Design and development	Controlled design/development planning, inputs, outputs, review, verification, validation, and change control — critical if the organization modifies, upgrades, or re-engineers equipment during refurbishment beyond the original manufacturer's design.
7.4	Purchasing	Evaluation and selection of suppliers based on their ability to supply conforming product/parts; purchasing information specifying requirements; verification of purchased product — directly relevant to sourcing donor units, spare parts, and components.
7.5	Production & service provision	Controlled production/refurbishment conditions; process validation where output cannot be fully verified by later inspection; installation and servicing requirements; identification and traceability (including UDI where applicable); customer property; preservation of product during handling, storage, and delivery.
7.6	Monitoring & measuring equipment	Calibration and verification of equipment used to confirm conformity, at defined intervals, traceable to a reference standard, with records maintained.
8.2	Feedback, complaints & vigilance	A defined process to gather post-market feedback, handle customer complaints, and report adverse events/incidents to relevant regulatory authorities where required.
8.2.4	Internal audit	Planned, periodic internal audits against the QMS and the standard, performed by personnel independent of the area audited, with follow-up on findings.
8.3	Nonconforming product	Identification, segregation, and disposition of product that does not meet requirements, including rework or scrap decisions and, where relevant, notification to affected parties (e.g. recall-type actions).
8.4–8.5	Analysis & improvement (CAPA)	Analysis of quality data to identify trends; corrective action to address root causes of nonconformities; preventive action to address potential nonconformities before they occur; documented effectiveness review of actions taken.

3. Relationship to Risk Management and Regulatory Frameworks

ISO 13485 does not stand alone — it is designed to interlock with risk management and regional regulation:

- **ISO 14971** (medical device risk management) is the expected risk-management framework referenced throughout ISO 13485 — risk-based thinking is expected in design, purchasing, production, and CAPA decisions rather than being a separate bolt-on activity.
- **Regional regulation** (e.g. EU MDR/IVDR, destination-country ministry of health rules) typically layers additional requirements on top of the QMS baseline — such as specific technical documentation, UDI/labeling rules, importer/authorized-representative obligations, and vigilance/incident reporting timelines — that ISO 13485 alone does not fully specify.
- **IEC 60601-1** and other product-safety standards address the safety and performance of the device itself, while ISO 13485 addresses the *management system* that ensures such requirements are consistently designed in, verified, and maintained. Certification bodies often expect evidence that both are addressed together.

4. Why This Matters for a Refurbishment & Export Business Specifically

- **Supplier/incoming control (Cl. 7.4):** donor-equipment sourcing, spare-part vendors, and sub-contracted repair services all need documented qualification and incoming verification.
- **Production/refurbishment control (Cl. 7.5):** refurbishment work instructions, functional/safety test steps, and acceptance criteria should be documented and followed consistently, not left to individual technician judgement.
- **Traceability (Cl. 7.5.9):** ability to trace a refurbished unit back to its donor source, parts used, and the technician/inspector responsible — important both for quality control and for responding to any future recall or complaint.
- **Design control (Cl. 7.3):** triggered if refurbishment involves modifications beyond the original manufacturer's specification (e.g. component substitution that changes performance) — this can shift the regulatory responsibility toward that of a manufacturer in some jurisdictions.
- **Complaint handling & vigilance (Cl. 8.2):** a defined channel for customers/end users in export markets to report problems, and a process to escalate serious issues appropriately.

5. Practical Field Checklists

Use these as a starting self-assessment and working-document set. They condense the general themes above into actionable items; they do not replace a formal gap assessment against the full standard text by a qualified quality/regulatory professional or certification body.

A. QMS Documentation & Document Control Checklist

Check Item / Action	Status
■ Quality manual exists, defines QMS scope, and references or includes required procedures.	Y / N / NA
■ Quality policy and measurable quality objectives documented and communicated to staff.	Y / N / NA
■ Document control procedure defines approval, review, and revision process for controlled documents.	Y / N / NA
■ Current-revision documents are available at points of use; obsolete versions are removed or clearly marked.	Y / N / NA
■ Record retention periods defined and followed (minimum: device lifetime or per applicable regulation).	Y / N / NA
■ Records are legible, identifiable, and retrievable when requested.	Y / N / NA
■ Management review meetings held at planned intervals with documented inputs and outputs.	Y / N / NA

B. Supplier & Incoming Material/Equipment Control Checklist

Check Item / Action	Status
■ Approved supplier list maintained, including donor-equipment sources and spare-parts vendors.	Y / N / NA
■ Supplier evaluation/re-evaluation criteria defined and applied (quality history, certifications, capability).	Y / N / NA
■ Purchasing documents specify clear requirements (specifications, standards, acceptance criteria) before goods/services are ordered.	Y / N / NA
■ Incoming inspection/verification performed and documented for donor equipment and critical spare parts.	Y / N / NA
■ Nonconforming incoming material identified, segregated, and dispositioned per procedure.	Y / N / NA
■ Records link each incoming lot/unit to its supplier and inspection results for traceability.	Y / N / NA

C. Production / Refurbishment Process Control Checklist

Check Item / Action	Status
■ Documented work instructions exist for each refurbishment/service process performed.	Y / N / NA
■ Acceptance criteria (functional, safety, cosmetic) defined for each process step.	Y / N / NA
■ Process validation performed for any step whose output cannot be fully verified by later inspection alone.	Y / N / NA
■ Personnel performing refurbishment/service are trained and competence is documented.	Y / N / NA
■ Work environment controls (cleanliness, ESD, contamination control) appropriate to the product are defined and followed.	Y / N / NA
■ Unique identification applied to each unit; traceability maintained from donor source through refurbishment steps to final shipment (including UDI where applicable).	Y / N / NA
■ Final acceptance testing performed and documented before release for shipment.	Y / N / NA
■ Packaging, labeling, and preservation during storage/delivery protect product integrity.	Y / N / NA

D. Design Control Checklist (if modifying beyond OEM spec)

Check Item / Action	Status
■ Design/development plan defined when refurbishment involves modification beyond original manufacturer specification.	Y / N / NA
■ Design inputs (functional, safety, regulatory requirements) documented before design work begins.	Y / N / NA
■ Design outputs documented and traceable back to inputs.	Y / N / NA
■ Design review conducted at appropriate stages with relevant functions represented.	Y / N / NA
■ Design verification confirms outputs meet inputs; design validation confirms the result meets user needs and intended use.	Y / N / NA
■ Design changes controlled, reviewed, and approved before implementation, with impact on already-shipped units considered.	Y / N / NA
■ Risk management file (per ISO 14971) updated to reflect any design change.	Y / N / NA

E. Monitoring & Measuring Equipment (Calibration) Checklist

Check Item / Action	Status
■ Inventory of all test/measuring equipment used to verify product conformity maintained.	Y / N / NA
■ Calibration intervals defined and documented for each instrument.	Y / N / NA
■ Calibration performed against a traceable reference standard; certificates retained.	Y / N / NA
■ Equipment found out of calibration triggers assessment of impact on previously tested/released product.	Y / N / NA
■ Calibration status clearly indicated on or near each instrument (label, tag, or system record).	Y / N / NA

F. Feedback, Complaints & Vigilance Checklist

Check Item / Action	Status
■ Defined channel exists for customers/end users to submit feedback or complaints.	Y / N / NA
■ Complaint log maintained with investigation status and outcome for each entry.	Y / N / NA
■ Criteria defined for when a complaint must be escalated as a potential adverse event/incident.	Y / N / NA
■ Process defined for reporting serious incidents to relevant national regulatory authorities within required timeframes.	Y / N / NA
■ Trends in feedback/complaints reviewed periodically as an input to CAPA and management review.	Y / N / NA

G. Internal Audit & CAPA Checklist

Check Item / Action	Status
■ Internal audit programme/schedule defined, covering all QMS processes over a defined cycle.	Y / N / NA
■ Auditors are independent of the area/process being audited.	Y / N / NA
■ Audit findings documented with objective evidence; nonconformities formally recorded.	Y / N / NA
■ Corrective action process requires root-cause analysis, not just symptom correction.	Y / N / NA
■ Preventive action process identifies and addresses potential (not-yet-occurred) nonconformities.	Y / N / NA
■ Effectiveness of corrective/preventive actions verified and documented after implementation.	Y / N / NA
■ Nonconforming product process defines identification, segregation, disposition (rework/scrap/return), and any necessary customer notification.	Y / N / NA

Reminder: *these checklists are a practical starting template for internal self-assessment. Certification, regulatory submissions, and formal audits must be based on the full official ISO 13485:2016 text and the specific requirements of the destination market's medical device regulation.*