
SELF-ASSESSMENT WORKSHEET

ISO 13485 — Medical Device Quality

Work through each clause, record what you do today, rate where you are and agree the actions that close the gap.

ORGANISATION

COMPLETED BY

DATE

How to rate: 0 = nothing in place 1 = partly in place 2 = in place, little evidence 3 = in place and evidenced
Fill in on screen or print. Always work from the current published standard.

How to complete this worksheet

1

Get the right people together

Ask the person who runs each area to help. Allow 1–2 hours per sitting; you don't have to finish in one go.

2

Read each clause and the evidence prompt

The grey box tells you what an auditor will look for. The examples underneath show the kind of records that count.

3

Write what you actually do today

Describe the real practice, not what you'd like to happen. Name the document, system or record and where it's kept, e.g. 'Training matrix — SharePoint/HR, updated monthly'.

4

Rate honestly from 0 to 3

0 nothing in place · 1 partly in place or informal · 2 in place but little written proof · 3 in place, followed and evidenced with records. If you can't show it, it isn't a 3.

5

Agree actions, owners and due dates

For anything rated 0–2, write the next practical step, who will do it and by when. Small, specific actions get done.

6

Summarise and review

List your top three priorities on the final page. Revisit the worksheet every few months to track progress.

What counts as good evidence?

- Good evidence is current, approved, dated and actually used — a policy nobody follows isn't evidence.
- Records beat documents: a completed checklist proves more than the procedure that describes it.
- Photos, screenshots, emails and system exports all count if they show the activity happening.
- Leave a box blank rather than guess — blanks show you where to look first.

CLAUSES 1-3

Scope, references and definitions

These opening clauses explain what ISO 13485 covers, list any documents it relies on and define its key terms. They contain no requirements you are audited against.

Evidence to look for: Read the definitions once — words like 'shall', 'interested party' and 'documented information' have precise meanings in an audit.

Examples of suitable evidence

- ✓ Copy of the current ISO 13485 standard
- ✓ Copy of ISO 9000 referenced by ISO 13485
- ✓ Staff glossary of medical device quality terms
- ✓ Briefing notes explaining the standard's scope

What we do today / evidence we hold**Actions to close the gap**

Owner

Due

Rating

0

1

2

3

CLAUSE 4

Context of the organisation

Define the quality system's scope and your regulatory role (manufacturer, distributor, importer), and document processes using a risk-based approach.

Evidence to look for: A quality manual and medical device file for each device type or family.

Examples of suitable evidence

- ✓ Quality manual stating system scope and justified exclusions
- ✓ Regulatory responsibilities register identifying manufacturer, importer or distributor roles
- ✓ Quality system process map showing interactions and responsibilities
- ✓ Risk assessments determining controls for outsourced quality system processes

What we do today / evidence we hold**Actions to close the gap**

Owner

Due

Rating

0

1

2

3

CLAUSE 5

Leadership

Top management sets quality policy, ensures regulatory requirements are met, appoints a management representative and conducts management review (5.6).

Evidence to look for: Management review records covering complaints, regulatory reporting and CAPA.

Examples of suitable evidence

- ✓ Quality policy signed by the managing director
- ✓ Management representative appointment letter defining responsibilities and authority
- ✓ Management review minutes recording decisions, resources and assigned actions
- ✓ Management meeting minutes reviewing applicable regulatory requirements and compliance

What we do today / evidence we hold**Actions to close the gap**

Owner		Due		Rating	0	1	2	3
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CLAUSE 6

Planning

Plan quality objectives and the quality system. Unlike ISO 9001, ISO 13485 keeps a strong emphasis on documented procedures and regulatory compliance.

Evidence to look for: Documented procedures for the activities the standard and regulations require.

Examples of suitable evidence

- ✓ Quality objectives register with measurable targets, owners and review dates
- ✓ Quality system implementation plan assigning responsibilities and deadlines
- ✓ Approved quality system change plan addressing continued system integrity
- ✓ Document control procedure covering approval, revision and access

What we do today / evidence we hold**Actions to close the gap**

Owner		Due		Rating	0	1	2	3
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CLAUSE 7**Support**

Resources, competence, infrastructure, work environment and contamination control (Clause 6 in this standard).

Evidence to look for: Cleanroom or environmental controls where products require them.

Examples of suitable evidence

- ✓ Staff competence matrix supported by training and assessment records
- ✓ Equipment maintenance log showing completed servicing and outstanding repairs
- ✓ Work environment monitoring records showing temperature and humidity checks
- ✓ Contamination control procedure with completed cleaning and hygiene inspection records

What we do today / evidence we hold**Actions to close the gap****Owner**

Due

Rating
☐ 0

☐ 1

☐ 2

☐ 3
CLAUSE 8**Operation**

Product realisation (Clause 7): risk management throughout, design and development controls, purchasing, production, sterilisation where relevant, traceability and control of monitoring equipment.

Evidence to look for: Design history, validation records, supplier controls and device traceability records.

Examples of suitable evidence

- ✓ Product risk management file with approved risk controls
- ✓ Design history file containing approved verification and validation reports
- ✓ Approved supplier register with purchasing specifications and supplier evaluation records
- ✓ Batch records linking components, sterilisation validation and calibrated inspection equipment

What we do today / evidence we hold**Actions to close the gap****Owner**

Due

Rating
☐ 0

☐ 1

☐ 2

☐ 3

CLAUSE 9**Performance evaluation**

Measurement, analysis and improvement (Clause 8): feedback, complaint handling, regulatory reporting, internal audit and monitoring of processes and product.

Evidence to look for: Complaint files, vigilance reports and trend analysis.

Examples of suitable evidence

- ✓ Customer feedback register with documented trend analysis
- ✓ Complaint files documenting investigations and regulatory reporting decisions
- ✓ Internal audit reports with findings and agreed actions
- ✓ Process monitoring reports and final product acceptance records

What we do today / evidence we hold**Actions to close the gap**

Owner		Due		Rating	0	1	2	3
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CLAUSE 10**Improvement**

Corrective and preventive action (CAPA) with documented investigation and effectiveness checks.

Evidence to look for: CAPA records linked to complaints, audits and nonconformities.

Examples of suitable evidence

- ✓ Approved corrective and preventive action procedure
- ✓ Corrective action report documenting root cause investigation and implemented actions
- ✓ Preventive action register recording potential problems and preventive measures
- ✓ CAPA effectiveness review records showing results and closure approval

What we do today / evidence we hold**Actions to close the gap**

Owner		Due		Rating	0	1	2	3
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NOTE

Different clause structure

ISO 13485:2016 follows the older clause structure (4-8) rather than the harmonised 4-10 layout; the plain-English topics above are mapped to its actual clauses.

Evidence to look for: Expect regulators and notified bodies to read it alongside the UK MDR or EU MDR/IVDR.

Examples of suitable evidence

- ✓ Copy of ISO 13485:2016 showing clauses 4-8
- ✓ Clause mapping table linking topic headings to actual standard clauses
- ✓ Staff briefing slides explaining the ISO 13485 clause structure
- ✓ Quality manual contents page referencing actual ISO 13485 clauses

What we do today / evidence we hold

Actions to close the gap

Owner		Due		Rating	0	1	2	3
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Summary and next steps

Top three priorities

Resources or support needed

Target date for certification or review

Want a second pair of eyes?

Send your completed worksheet to our success team for a free review call.

success@isology.co.uk · www.isology.co.uk/contact