

GOVERNANCE DOCS

ISO 13485:2016

Gap Assessment Report

ISO 13485:2016 Medical Devices Quality Management System

Clearview Medical Devices (sample)

Design, manufacture and distribution of single-use diagnostic devices.

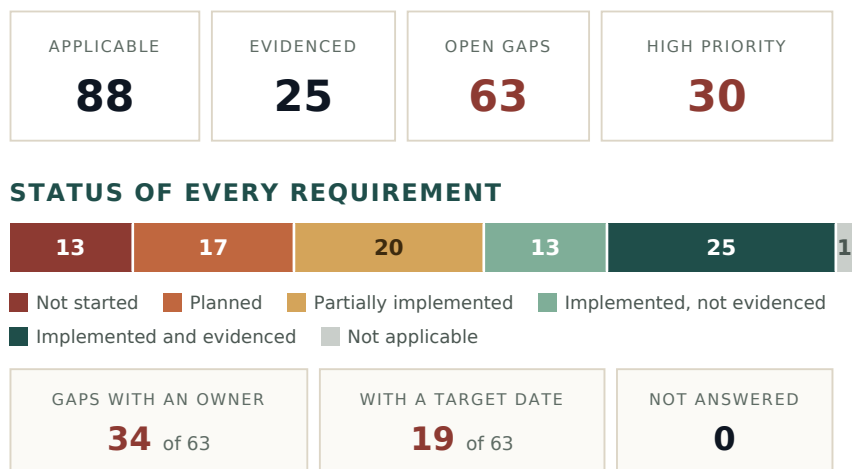
ASSESSED	25 September 2026
EDITION	2016 (third edition, confirmed by systematic review in 2025)
IN SCOPE	89 requirements, 88 applicable
PROFILE	Healthcare and life sciences · 10 to 49 people
PREPARED BY	Governance Docs

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Confidential. Prepared for Clearview Medical Devices (sample) from its own self-assessment; not independently verified by Governance Docs (see section A). Share on a need-to-know basis.

Where Clearview Medical Devices (sample) stands against ISO 13485



WHAT THIS ASSESSMENT TELLS YOU

- Overall readiness is 55.7% against ISO 13485 across 88 applicable controls. 25 of them are implemented and evidenced.
- Most open gaps: Clause 8 - Measurement, analysis and improvement, with 14 at 30%. Strongest area: Clause 7 - Product realization at 82%.
- 4 management-system clauses score under half: Clause 4 - Quality management system (33%); Clause 5 - Management responsibility (43%); Clause 6 - Resource management (0%); Clause 8 - Measurement, analysis and improvement (30%). Clauses cannot be excluded, and each is a likely major nonconformity at a certification audit.
- 13 controls are operating but not evidenced. Collecting their records alone lifts the score to 59.4% (+3.7 points), the cheapest gain available.
- 30 gaps are high priority (not started or only planned); 11 of them are in Clause 8 - Measurement, analysis and improvement.

DO THESE FIRST

	PRIORITY	ACTION	OWNER	START FROM
1	HIGH	Bring every management-system clause above 50%, starting with 4.1.1 General requirements; 5.2 Customer focus; 6.2 Human resources and 1 more	Risk Manager	QMS-001 Quality Manual
2	HIGH	Put an owner and date against the 11 high-priority gaps in Clause 8 - Measurement, analysis and improvement	Compliance Lead	MAI-006 Control of Nonconforming Product Procedure
3	MEDIUM	Adopt and tailor the QMS-001 Quality Manual, which closes 4 open gaps	To assign	QMS-001 Quality Manual

Analysis and priorities

IN ONE SENTENCE

With an overall score of 55.7%, the organization must establish foundational resource and quality management controls to address 63 open gaps.

AI-assisted analysis, generated from the information the organization provided and checked automatically against the scores and findings in this report. It supports planning and is not an audit opinion; see "Basis of this report and limitation of liability".

FOR SENIOR MANAGEMENT AND THE BOARD

The organization stands at a Developing readiness level with an overall score of 55.7% across 88 applicable requirements. Our primary exposure stems from 30 high priority gaps, including zero percent implementation in resource management and weak measurement controls. Senior leadership must immediately support the quality programme by approving essential governance policies, assigning formal owners to all 63 open gaps, and ensuring operational teams allocate time to document existing practices over the next 90 days.

WHERE YOU STAND

The self-assessment places the organization at readiness level 2 of 4, named Developing, with an overall score of 55.7%. Out of 88 applicable requirements, 63 remain open gaps, and 30 of these are high priority. Clause 7 - Product realization is the strongest area at 81.7%. In contrast, Clause 6 - Resource management is at 0%, Clause 8 - Measurement, analysis and improvement is at 30.4%, and Clause 4 - Quality management system is at 33.3%. Only 34 gaps have an assigned owner.

WHAT IT MEANS FOR THE ORGANIZATION

The pattern indicates that core operational delivery in product realization has outpaced the governing management system. With Clause 6 - Resource management unstarted and Clause 8 - Measurement, analysis and improvement mostly planned, the organization lacks formal mechanisms to track personnel competence, calibrate infrastructure, log customer complaints, or capture nonconforming product. In a formal review, these omissions represent material findings. Operational competence currently rests on informal practices rather than documented, verifiable processes.

WHERE TO FOCUS FIRST

Immediate effort should target the 13 requirements that are implemented but not evidenced, which will raise the score to 59.4%. Next, completing the 20 partially implemented requirements will advance the score to 70.7%. The organization should focus initial documentation efforts on releasing the Quality Manual and the QMS & Process Interaction Procedure, as these establish foundational system architecture. Management must also assign named owners and target dates to all 30 high priority gaps to ensure accountability across the 63 open gaps.

1 · EXECUTIVE SUMMARY

PRIORITIES

	PRIORITY	WHY IT MATTERS	FIRST STEP	START FROM	WITHIN
1	Establish human resource competence and training procedures Clause 6 - Resource management · 6.2 Human resources	Clause 6 - Resource management is at 0%, meaning training and qualification records are not formalized. This exposes the organization to material findings regarding staff competence in regulated healthcare activities.	Adopt the human resources procedure and compile existing staff qualification records into the training matrix.	RES-001 Human Resources & Competence Procedure ISO 13485 Toolkit - Comprehensive 126 Templates	30 DAYS
2	Finalize and approve the overarching quality manual 4.1.1 General requirements · 4.2.2 Quality manual	Clause 4 - Quality management system stands at 33.3% with 9 open gaps. Establishing the quality manual defines the scope, structure, and operational process interactions across the organization.	Draft the quality manual sections outlining the quality management system scope and process interactions.	QMS-001 Quality Manual ISO 13485 Toolkit - Comprehensive 126 Templates	30 DAYS
3	Implement nonconforming product and corrective action procedures 8.3.1 Control of nonconforming product · 8.5.3 Preventive action	Clause 8 - Measurement, analysis and improvement is at 30.4% with 14 open gaps. Uncontrolled nonconformances and missing corrective procedures prevent effective resolution of product defects.	Distribute the nonconforming product procedure and make the nonconformity report template available to operations.	MAI-006 Control of Nonconforming Product Procedure ISO 13485 Toolkit - Comprehensive 126 Templates	60 DAYS
4	Define applicable regulatory requirements and justifications SC.2 Applicable regulatory requirements identified · SC.3 Exclusions and non-applications justified	Scope and regulatory role scored 43.8% with 3 open gaps. Failing to formalize regulatory expectations and exclusions risks misaligned compliance across markets.	Populate the regulatory register with current applicable statutory and regulatory obligations.	REG-006 Applicable Regulatory Requirements Register (Word + Excel) ISO 13485 Toolkit - Comprehensive 126 Templates	60 DAYS
5	Establish internal audit and complaint handling mechanisms 8.2.2 Complaint handling · 8.2.4 Internal audit	Internal audits and complaint management remain in planned status rather than active execution, preventing proactive detection of system failures.	Approve the internal audit procedure and draft the audit plan and schedule.	MAI-001 Internal Audit Procedure ISO 13485 Toolkit - Comprehensive 126 Templates	90 DAYS

30 / 60 / 90-DAY ROADMAP**FIRST 30 DAYS**

- Gather documented evidence for the 13 implemented requirements to reach a 59.4% score.
- Approve and issue the Quality Manual to define quality management system structure.
- Release the human resources procedure and establish baseline training records.

DAYS 31 TO 60

- Deploy the control of nonconforming product procedure and logging forms.
- Populate the applicable regulatory requirements register with current operational obligations.
- Complete implementation across the 20 partially implemented requirements to reach 70.7%.

DAYS 61 TO 90

- Roll out the corrective and preventive action procedure and tracking register.
- Establish the internal audit procedure, plan, and schedule.
- Implement the complaint handling procedure and establish the central complaint log.

Maturity across the standard

Each bar shows how the requirements in one area break down by status, weakest on the left. The score is the average across applicable requirements; the chips count open gaps by priority.

OTHER REQUIREMENTS	STATUS MIX	SCORE	GAPS H · M · L
Scope and regulatory role	2 1 1	44%	2 0 1
MANAGEMENT SYSTEM CLAUSES	STATUS MIX	SCORE	GAPS H · M · L
Clause 4 - Quality management system	2 3 3 1	33%	5 3 1
Clause 5 - Management responsibility	2 3 2 4	43%	5 2 4
Clause 6 - Resource management	4	0%	4 0 0
Clause 7 - Product realization	8 3 18	82%	1 8 3
Clause 8 - Measurement, analysis and improvement	3 8 3	30%	11 0 3
OTHER REQUIREMENTS	STATUS MIX	SCORE	GAPS H · M · L
FDA QMSR overlay	1 1 1 4	79%	1 1 1
EU MDR and IVDR overlay	6 2	58%	1 6 0

■ Not started ■ Planned ■ Partially implemented ■ Implemented, not evidenced ■ Implemented and evidenced ■ Not applicable

WHERE THE NEXT POINTS COME FROM

The score after each kind of work, cheapest first. Gold is what that step adds.

Today		55.7%
Evidence what already runs 13 requirements		59.4% +3.7
Finish what is partly in place 20 requirements		70.7% +11.3
Implement what is planned 17 requirements		85.2% +14.5
Start what has not begun 13 requirements		100.0% +14.8

DOCUMENTS THAT CLOSE THE MOST GAPS

Each bar counts the open gaps that name the document as the way to close them.

QMS-001 Quality Manual		4
QMS-002 QMS & Process Interaction Procedure		4
MGT-004 Management Review Input & Minutes Template		4
FBK-001 Feedback & Post-Market Surveillance (PMS) Procedure		3
REG-006 Applicable Regulatory Requirements Register (Word + Excel)		2
PUR-001 Purchasing & Supplier Control Procedure		2

All of these are in the ISO 13485 Toolkit (104 documents).

Every open gap, grouped by what has to happen next

Work from the top. Requirements not yet started or only planned are the ones a certification auditor reaches first; the last group already operates and needs only its records.

HIGH Not started · 13

Start from a documented baseline: adopt and tailor the document named below, then put it into operation.

Ref	Requirement	Area	Owner · target	Closes it
SC.2	Applicable regulatory requirements identified	Scope and regulatory role	To assign	REG-006 Applicable Regulatory Requirements Register (Word + Excel)
SC.3	Exclusions and non-applications justified	Scope and regulatory role	Risk Manager 7 Jan 2027	REG-007 Statement of Applicability & Justification of Non-Applicable Requirements · QMS-001 Quality Manual
4.1.1	General requirements	Clause 4	To assign	QMS-001 Quality Manual · QMS-002 QMS & Process Interaction Procedure
4.1.6	Validation of QMS software	Clause 4	Risk Manager 7 Jan 2027	QMS-007 QMS Software / Computer System Validation Procedure · QMS-F03 QMS Software Inventory & Validation Register
5.2	Customer focus	Clause 5	Compliance Lead	MGT-001 Quality Policy
5.5.1	Responsibility and authority	Clause 5	HR Manager	MGT-005 Roles, Responsibilities & Authorities Matrix (RACI) · MGT-F01 Job Description Form
6.2	Human resources	Clause 6	Operations Manager	RES-001 Human Resources & Competence Procedure · RES-002 Training Plan & Competence Matrix / Register (Word + Excel) +1 more
6.3	Infrastructure	Clause 6	Risk Manager	RES-004 Infrastructure & Maintenance Procedure · RES-F02 Equipment Maintenance Record
6.4.1	Work environment	Clause 6	To assign	RES-005 Work Environment & Contamination Control Procedure
6.4.2	Contamination control	Clause 6	To assign	RES-005 Work Environment & Contamination Control Procedure · PRD-002 Cleanliness of Product & Contamination Control Procedure

8.3.1	Control of nonconforming product	Clause 8	To assign	MAI-006 Control of Nonconforming Product Procedure · MAI-007 Nonconformity Report (NCR) Template
8.4	Analysis of data	Clause 8	To assign	MAI-009 Analysis of Data Procedure
8.5.3	Preventive action	Clause 8	Compliance Lead 29 Oct 2026	MAI-010 Corrective & Preventive Action (CAPA) Procedure · MAI-011 CAPA Request & Tracking Register (Word + Excel)

HIGH Planned · 17

Move from plan to implementation. Assign an owner and a date, then put the control into operation.

Ref	Requirement	Area	Owner · target	Closes it
4.1.2	Processes and risk-based approach	Clause 4	Operations Manager	QMS-002 QMS & Process Interaction Procedure · QMS-F04 Key Process Master List
4.1.4	Changes to the quality management system	Clause 4	Risk Manager	QMS-002 QMS & Process Interaction Procedure · QMS-F01 Document Change Request Form
4.2.2	Quality manual	Clause 4	To assign	QMS-001 Quality Manual
5.4.2	Quality management system planning	Clause 5	Operations Manager	MGT-F02 QMS Planning Worksheet · QMS-002 QMS & Process Interaction Procedure
5.5.3	Internal communication	Clause 5	Operations Manager	MGT-007 Internal Communication Procedure
5.6.3	Management review outputs	Clause 5	To assign	MGT-004 Management Review Input & Minutes Template
7.5.3	Installation activities	Clause 7	Operations Manager 24 Dec 2026	PRD-003 Installation Activities Procedure
8.2.1	Feedback	Clause 8	HR Manager 29 Oct 2026	FBK-001 Feedback & Post-Market Surveillance (PMS) Procedure · FBK-F01 Customer Satisfaction / Feedback Survey
8.2.2	Complaint handling	Clause 8	HR Manager	FBK-002 Complaint Handling Procedure · FBK-003 Complaint Register / Log (Word + Excel)
8.2.4	Internal audit	Clause 8	To assign	MAI-001 Internal Audit Procedure · MAI-002 Internal Audit Plan & Schedule Template +2 more
8.2.5	Monitoring and measurement of processes	Clause 8	Risk Manager 7 Jan 2027	MAI-005 Monitoring & Measurement of Processes & Product Procedure · MAI-F02 Product/Process Monitoring & Analysis Table

8.2.6	Monitoring and measurement of product	Clause 8	Operations Manager	MAI-005 Monitoring & Measurement of Processes & Product Procedure
8.3.3	Nonconformity after delivery	Clause 8	Compliance Lead 12 Nov 2026	FBK-005 Advisory Notice, Field Safety Corrective Action & Recall Procedure
8.3.4	Rework	Clause 8	HR Manager 10 Dec 2026	MAI-008 Rework Procedure
8.5.1	Improvement - general	Clause 8	Compliance Lead 4 Feb 2027	MAI-009 Analysis of Data Procedure
QMSR.2	Certification is not compliance	FDA QMSR overlay	Risk Manager	REG-005 ISO 13485 Certification / MDSAP Readiness Checklist (Word + Excel)
EU.8	Trend reporting and field safety	EU MDR and IVDR overlay	HR Manager	FBK-005 Advisory Notice, Field Safety Corrective Action & Recall Procedure

MEDIUM Partially implemented · 20

Extend the existing approach to the whole scope and apply it consistently, then evidence it.

Ref	Requirement	Area	Owner · target	Closes it
4.1.5	Outsourced processes	Clause 4	Risk Manager 7 Jan 2027	QMS-008 Control of Outsourced Processes Procedure · PUR-001 Purchasing & Supplier Control Procedure
4.2.4	Control of documents	Clause 4	Risk Manager	QMS-003 Control of Documents Procedure · QMS-006 Master Document & Record List / Register (Word + Excel)
4.2.5	Control of records	Clause 4	HR Manager	QMS-004 Control of Records Procedure · QMS-006 Master Document & Record List / Register (Word + Excel)
5.3	Quality policy	Clause 5	Risk Manager 26 Nov 2026	MGT-001 Quality Policy
5.6.2	Management review inputs	Clause 5	To assign	MGT-004 Management Review Input & Minutes Template
7.2.1	Determination of requirements	Clause 7	To assign	CRP-002 Customer-Related Processes Procedure
7.3.1	Design and development - general	Clause 7	Compliance Lead 24 Dec 2026	DES-001 Design & Development Control Procedure
7.3.7	Design validation	Clause 7	HR Manager 7 Jan 2027	DES-007 Design Validation Protocol & Report Template · DES-013 Clinical Evaluation / Clinical Evidence Procedure (MDR Annex XIV)

7.4.1	Purchasing process	Clause 7	To assign	PUR-001 Purchasing & Supplier Control Procedure · PUR-002 Supplier Evaluation, Selection & Re-evaluation Procedure +1 more
7.4.2	Purchasing information	Clause 7	To assign	PUR-004 Purchasing Information / Requirements Specification Template
7.5.4	Servicing activities	Clause 7	Compliance Lead 7 Jan 2027	PRD-004 Servicing Activities Procedure · FBK-001 Feedback & Post-Market Surveillance (PMS) Procedure
7.5.5	Sterile medical devices	Clause 7	Operations Manager 24 Dec 2026	STE-001 Sterile Medical Devices Control Procedure
7.5.10	Customer property	Clause 7	IT Manager 29 Oct 2026	PRD-008 Customer Property Procedure · PRD-F04 Customer Property Control Log
QMSR.1	QMSR applicability	FDA QMSR overlay	Operations Manager	REG-001 ISO 13485:2016 to FDA QMSR (21 CFR Part 820) Cross-Reference Matrix (Word + Excel)
EU.3	General safety and performance requirements	EU MDR and IVDR overlay	To assign	REG-002 ISO 13485:2016 to EU MDR 2017/745 Cross-Reference Matrix (Word + Excel)
EU.5	Clinical evaluation and post-market clinical follow-up	EU MDR and IVDR overlay	To assign	DES-013 Clinical Evaluation / Clinical Evidence Procedure (MDR Annex XIV)
EU.6	Post-market surveillance and periodic reporting	EU MDR and IVDR overlay	Operations Manager 4 Feb 2027	FBK-001 Feedback & Post-Market Surveillance (PMS) Procedure
EU.7	Vigilance clocks	EU MDR and IVDR overlay	To assign	FBK-004 Regulatory Reporting & Vigilance Procedure (FDA MDR / EU MDR / IMDRF)
EU.9	Unique device identification and registration	EU MDR and IVDR overlay	Compliance Lead 26 Nov 2026	PRD-007 Unique Device Identification (UDI) & Labelling Control Procedure
EU.10	Declaration of conformity and CE marking	EU MDR and IVDR overlay	Compliance Lead 7 Jan 2027	REG-002 ISO 13485:2016 to EU MDR 2017/745 Cross-Reference Matrix (Word + Excel)

LOW Implemented, not evidenced · 13

Collect and file evidence an auditor can sample. The control is operating; what is missing is the record of it.

Ref	Requirement	Area	Owner · target	Closes it
SC.1	Roles undertaken	Scope and regulatory role	To assign	QMS-001 Quality Manual · REG-006 Applicable Regulatory Requirements Register (Word + Excel)
4.2.3	Medical Device File	Clause 4	To assign	QMS-005 Medical Device File Procedure & Index · PRD-010 Device Master Record (DMR) / Production Specification Index

5.1	Management commitment	Clause 5	To assign	MGT-003 Management Review Procedure · MGT-004 Management Review Input & Minutes Template
5.4.1	Quality objectives	Clause 5	To assign	MGT-002 Quality Objectives & KPI Register (Word + Excel)
5.5.2	Management representative	Clause 5	To assign	MGT-006 Management Representative Appointment & Duties
5.6.1	Management review	Clause 5	To assign	MGT-003 Management Review Procedure
7.2.2	Review of requirements	Clause 7	To assign	CRP-003 Customer Requirements Review Record Template
7.5.1	Control of production and service provision	Clause 7	To assign	PRD-001 Control of Production & Service Provision Procedure · PRD-F01 Process Routing / Traveler Sheet
7.5.9.1	Traceability - general	Clause 7	To assign	PRD-006 Identification & Traceability Procedure · PRD-F03 Traceability / Serial-Number Log
8.2.3	Reporting to regulatory authorities	Clause 8	To assign	FBK-004 Regulatory Reporting & Vigilance Procedure (FDA MDR / EU MDR / IMDRF)
8.3.2	Nonconformity before delivery	Clause 8	To assign	MAI-007 Nonconformity Report (NCR) Template
8.5.2	Corrective action	Clause 8	To assign	MAI-010 Corrective & Preventive Action (CAPA) Procedure · MAI-011 CAPA Request & Tracking Register (Word + Excel)
QMSR.3	Records previously exempt are now inspectable	FDA QMSR overlay	To assign	MGT-004 Management Review Input & Minutes Template · MAI-004 Internal Audit Report & Finding Tracking Template

How it was scored

STATUS WEIGHTS

Status	Weight	Meaning
■ Not started	0.00	No policy, process or activity exists for this requirement.
■ Planned	0.25	Approach agreed and scheduled, but nothing is in place yet.
■ Partially implemented	0.50	In place for part of the scope, or inconsistently applied.
■ Implemented, not evidenced	0.75	Operating as intended, but you could not prove it to an auditor today.
■ Implemented and evidenced	1.00	Operating as intended, with records an auditor can sample.
■ Not applicable	—	A justified exclusion. Removed from the score - record why in your notes.

READINESS LEVELS

1 • Initial (0%+)

Most requirements are not yet in place. Build the foundations before thinking about an audit.

2 • Developing (40%+)

The programme is under way, with material gaps an auditor would find.

3 • Established (65%+)

Most controls operate. Remaining work is closing specific gaps and evidencing what runs.

4 • Audit-ready (85%+)

Controls operate and are evidenced. Ready for an internal audit and a certification body.

A management-system clause scoring under 50% holds the level at Developing, because clauses cannot be excluded from certification scope.

WHAT THIS REPORT IS

BASIS OF THIS REPORT AND LIMITATION OF LIABILITY

This report is the output of a self-assessment. The scores, readiness levels, gaps, analysis and recommendations in this report are derived solely from the information entered by the organization, and have not been independently reviewed, verified, tested or audited by Governance Docs. Governance Docs did not conduct an independent assessment of the organization, its controls or its operations.

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A control that is running but cannot be evidenced scores 0.75, not 1.00. Auditors sample records, not intentions. Closing that distance is usually the fastest route to a higher score.

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YOUR WORKBOOK

The Excel workbook that comes with this report follows the same sections and colours. Dashboard: sections 1 and 2, recalculated live. Assessment: every requirement; change a status and every score, chart and level updates. Remediation Plan: section 3, with owners, dates and progress since this report. How it was scored: this page.

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