

ISO 13485 Implementation and Certification Readiness Checklist

High-level evidence screening tool

Use this checklist to test whether core ISO 13485 processes are defined, operating, and supported by objective evidence. Mark the current state, note the evidence reviewed, and record the next action.

ORGANIZATION

QMS SCOPE

REVIEW DATE

REVIEWER

IMPLEMENTATION AND EVIDENCE CHECK	Y	P	N	N/A	EVIDENCE / RECORD	GAP / ACTION
1. Scope and QMS foundation						
The QMS scope matches our legal role, sites, products, activities, markets, and permitted non-applicability decisions.	☐	☐	☐	☐		
Core processes, interactions, responsibilities, controlled documents, records, and medical device files are current and traceable.	☐	☐	☐	☐		
2. Leadership and resources						
Quality objectives, responsibilities, and management review decisions are current, measurable, assigned, and followed through.	☐	☐	☐	☐		
Personnel competence, training effectiveness, infrastructure, and applicable work-environment controls are supported by records.	☐	☐	☐	☐		
3. Product realization and risk						
Planning, design, purchasing, production, acceptance, change, traceability, preservation, and service controls operate where applicable.	☐	☐	☐	☐		
ISO 14971 risk outputs are connected to design, supplier, production, change, complaint, and CAPA controls where relevant.	☐	☐	☐	☐		
4. Suppliers, outsourced work, and software						
Critical suppliers and outsourced processes are risk-ranked, qualified, monitored, re-evaluated, and governed by clear requirements.	☐	☐	☐	☐		
Software used in the QMS has a defined intended use, risk assessment, validation evidence where required, and controlled changes.	☐	☐	☐	☐		
5. Measurement and improvement						
Audits, feedback, complaints, nonconformities, regulatory reporting, CAPA, and data analysis produce timely, consistent evidence.	☐	☐	☐	☐		
Open actions have owners and due dates; root causes are supported; effectiveness checks show whether recurrence was prevented.	☐	☐	☐	☐		
6. Certification readiness						
Process owners can explain actual practice and retrieve recent, complete records that agree with procedures and each other.	☐	☐	☐	☐		
The planned certification scope, sites, readiness timing, unresolved gaps, and audit arrangements have been reviewed with stakeholders.	☐	☐	☐	☐		

Readiness interpretation

Mostly Yes:

Core controls appear established. Close remaining actions and test records before the external audit.

Several Partial:

Implementation is uneven. Assign owners, create evidence, and verify effectiveness before scheduling.

Any critical No:

Treat as a readiness blocker where it affects scope, product conformity, regulatory duties, or system effectiveness.