



MEDICAL DEVICE / REGULATORY & QUALITY

Achieving and Sustaining Class IIb Compliance for a Medical Software Device

Clinical evaluation, software lifecycle compliance,
change control and ongoing regulatory support

1

EU MDR
Class IIb

2

Clinical
Evaluation

3

IEC 62304
Software Lifecycle

4

ISO 13485
QMS

5

DQS
Assessment

A successful EU conformity assessment supported by integrated clinical, software and quality evidence.

01 Overview

A connected regulatory and quality engagement across the software device lifecycle.



A medical technology manufacturer required regulatory and quality support for a Class IIb Medical Device Software (MDSW), including clinical evaluation, software lifecycle controls and continued certification readiness.

Elexes provided ongoing support across EU MDR requirements, ISO 13485 quality management, IEC 62304 software lifecycle documentation, applicable FDA device-software requirements and the DQS Notified Body assessment.

ENGAGEMENT OUTCOME

Class IIb CE marking achieved, with clinical evaluation updated and continuing software and quality compliance supported.

02 The Client Requirement

Certification was the milestone; sustained control of evolving Medical Device Software (MDSW) was the long-term requirement.

01

Clinical evidence

Update the CER based on relevant new clinical information, PMS/PMCF outputs, state-of-the-art review and device changes, as applicable.

02

Software compliance

Maintain IEC 62304 lifecycle documentation, software V&V records and applicable FDA QMSR/device-software documentation.

03

QMS and audits

Sustain ISO 13485 processes and preparedness for regular and applicable MDSAP audits.

04

Change management

Assess software changes, support review and approval of engineering change records, and evaluate regulatory impact.

03 Key Challenges

Maintaining a defensible evidence base while the software, clinical information and regulatory obligations evolved.

01 Clinical evaluation updates

New clinical information required assessment and appropriate revisions to the CER.

02 Controlled software evolution

Each change needed review for potential effects on functionality, clinical evidence, V&V and risk.

03 Multiple regulatory frameworks

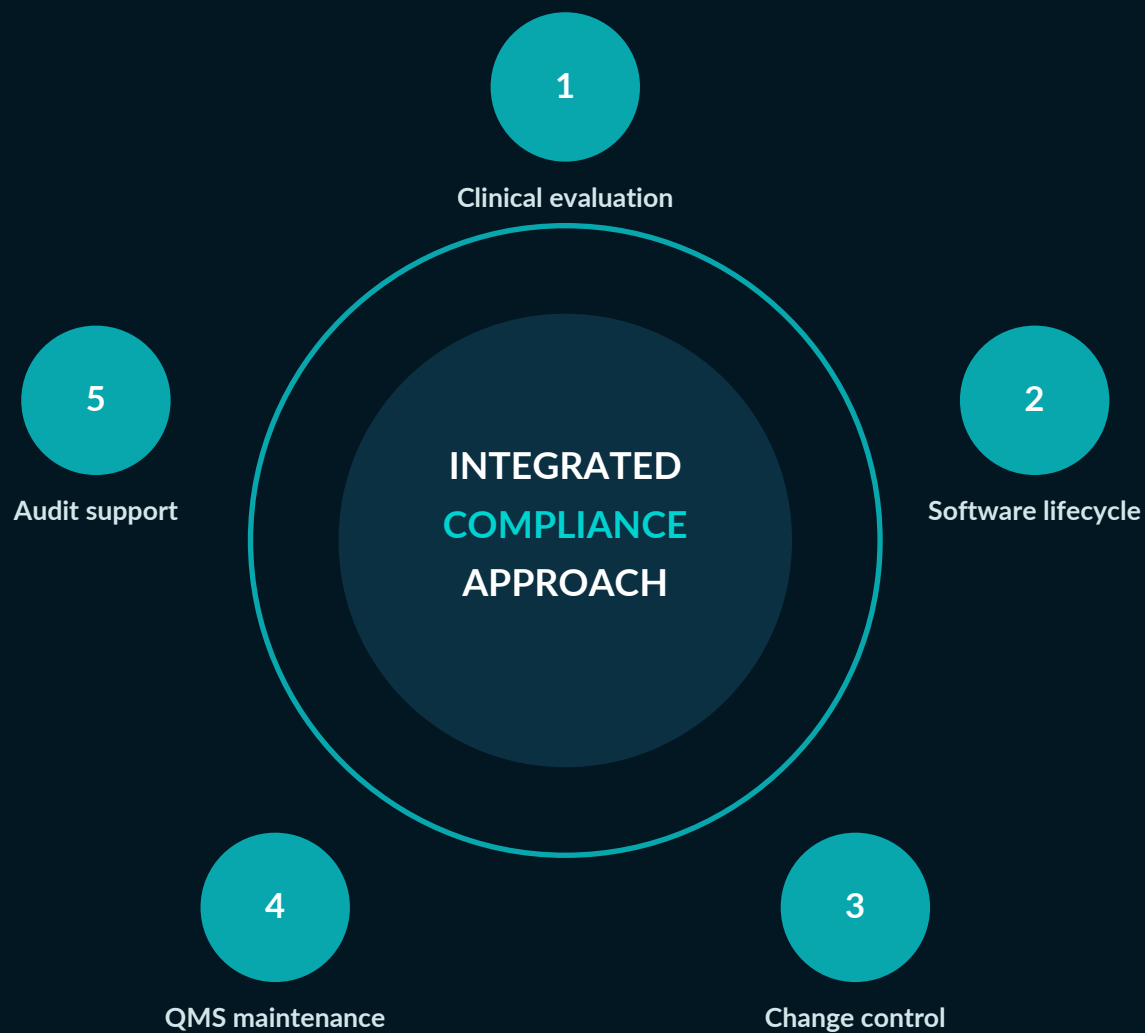
Quality and software processes needed to remain consistent across EU MDR, ISO 13485, IEC 62304 and applicable FDA requirements.

04 Repeatable audit readiness

Current records were needed for DQS Notified Body review and periodic quality assessments.

04 Elexes' Approach

An integrated regulatory, clinical and quality management model.



The compliance model connected updated clinical evidence, controlled software releases, maintained QMS records and review-ready documentation throughout the device lifecycle.

05 Methodology

Six connected workstreams: from assessment through ongoing compliance maintenance.

01

Regulatory and quality assessment

Mapped applicable obligations and reviewed existing controlled documentation.

02

Clinical evaluation development

Updated the CER based on relevant new clinical information, PMS/PMCF outputs, state-of-the-art review and device changes, as applicable.

03

IEC 62304 lifecycle support

Maintained software evidence, V&V records and traceability-related documentation.

04

Engineering change assessment

Documented changes, completed impact reviews and followed approval controls.

05

External audit and assessment support

Prepared updated evidence and supported responses to assessment observations.

06

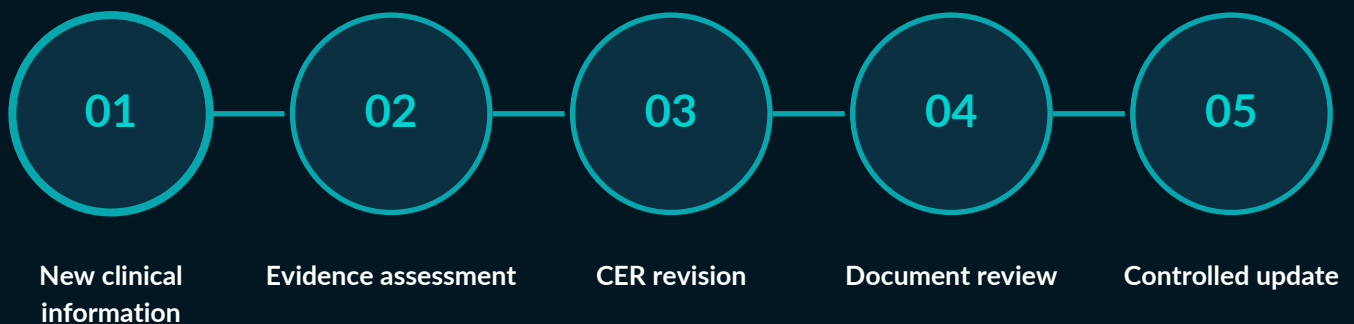
Continuing compliance maintenance

Maintained controlled records and evaluated regulatory actions for changes.

06 Clinical Evaluation

Maintaining a current CER as the device and its clinical evidence evolved.

Elexes prepared the Clinical Evaluation Report (CER) and updated it based on relevant new clinical information, PMS/PMCF outputs, state-of-the-art review and device changes, as applicable. These revisions kept the clinical evidence aligned with the device's intended purpose and current documented characteristics.

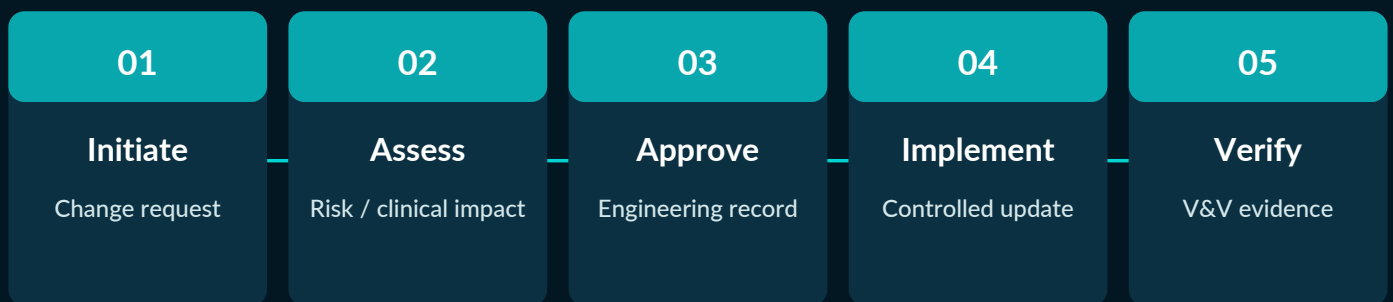


CLINICAL EVIDENCE AND SOFTWARE CHANGES

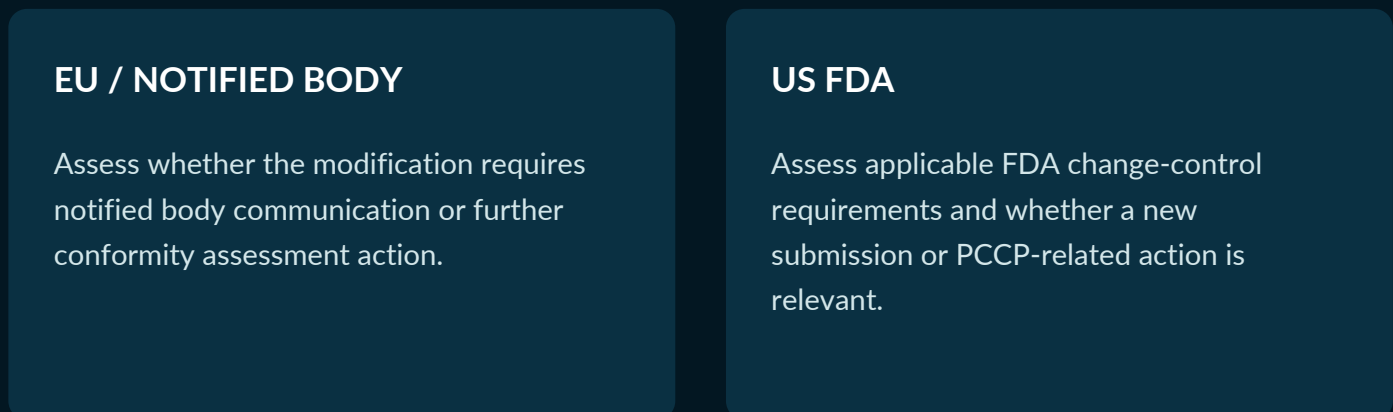
Clinical evidence maintenance was coordinated with software lifecycle and change-control processes. Where new evidence or modifications were relevant to the device's documented characteristics, associated regulatory and quality records were evaluated for update.

07 Software Change Control

A documented engineering change pathway with review, approval and regulatory impact assessment.



REGULATORY DECISION PATH



Approved changes were reflected in relevant lifecycle, quality and regulatory records, supporting consistency with the currently released software configuration.

08 Quality and Audit Support

ISO 13485 processes, software records and compliance evidence maintained for recurring external review.



Document control

Controlled and current clinical, regulatory and lifecycle records.

Audit evidence

Supporting records prepared for ISO 13485 and applicable MDSAP review.

Regulatory interaction

ISO 13485 assessment support and structured responses to review observations.

Ongoing maintenance

Changes reflected in approved documentation and applicable quality processes.

09 Results and Impact

Class IIb conformity achieved, supported by continuing clinical, software and quality evidence.

CLASS IIb

CE MARKING ACHIEVED

Successful EU conformity assessment with the DQS Notified Body, supported by Elexes' clinical evaluation and regulatory / quality compliance activities.

1

CER PREPARED & UPDATED

CER updated using clinical information, PMS/PMCF, state-of-the-art evidence and device changes, as applicable.

2

LIFECYCLE COMPLIANCE

IEC 62304 lifecycle documentation, software V&V and applicable FDA QMSR/device-software records maintained.

3

CHANGE CONTROL IN PLACE

Engineering change assessments and review / approval processes supported.

4

AUDIT READINESS MAINTAINED

ISO 13485 quality evidence and recurring assessment support provided.

10 Broader Relevance

Where this experience supports other medical software manufacturers.

1

MDSW lifecycle maintenance

IEC 62304 records, V&V evidence and controlled releases.

2

Clinical evaluation services

CER development, evidence updates and ongoing clinical evaluation.

3

EU CE-marking support

Class IIa / IIb technical evidence and notified body interactions.

4

FDA software change assessment

Submission impact reviews and PCCP-related planning where applicable.

5

ISO 13485 and MDSAP

QMS maintenance, audit preparation and corrective action support.

6

Connected and evolving software

Integrated regulatory, quality and risk assessment as devices change.

11 What This Means for Medical Device Software

Regulatory compliance is a lifecycle discipline, not a one-time certification exercise.



For an evolving medical software device, each release, clinical evidence update and regulatory decision can have implications across multiple records and obligations.

This engagement shows the value of bringing together clinical evaluation, IEC 62304 software lifecycle controls, ISO 13485 quality processes, engineering change management and notified body readiness within a coherent compliance framework.

Elexes supported the manufacturer through successful Class IIb CE marking and the ongoing compliance activities needed as its Medical Device Software continued to evolve.