

Strengthening Software Lifecycle Compliance for a Connected Diagnostic Device

IEC 62304 / Software V&V / Cybersecurity / Risk management



A CONNECTED POINT-OF-CARE HEMOGLOBIN MEASUREMENT SYSTEM

Complete software documentation and TÜV assessment support contributed to CE marking for Class B IVD medical device software under Regulation (EU) 2017/746 (IVDR).

Overview

Client requirement / device context / regulatory objective

WHAT THE CLIENT NEEDED

A manufacturer developing a connected point-of-care hemoglobin measurement system required complete software documentation to support conformity assessment and CE marking under Regulation (EU) 2017/746 (IVDR) for Class B IVD medical device software.

THE DEVICE



Illustrative diagnostic system

The system included embedded firmware, measurement-related functions, calibration logic, regional configurations and Bluetooth Low Energy (BLE) connectivity. The software evidence needed to accurately reflect how these elements worked together.

REGULATORY SETTING

The manufacturer underwent a TÜV-involved conformity assessment under Regulation (EU) 2017/746 (IVDR). Elexes supported the software lifecycle documentation against IEC 62304 expectations, integrating verification, risk management, cybersecurity and controlled technical revisions.

CONFIRMED OUTCOME CLASS B IVD • IVDR CE MARKING • PROJECT CLOSED

The Client's Challenge

A technically accurate and traceable body of software evidence, not simply individual files



01 Complex architecture and configurations

Software requirements and design records needed to describe standalone device boundaries, calibration logic, operating states and market-specific configurations consistently.

02 Verification and traceability

Software test cases, unit-test evidence and documented functions had to be linked so the reviewer could follow the technical basis for verification.

03 Cybersecurity and risk controls

BLE security, AES-128 encryption, protected interfaces and software hazards required technically coherent descriptions across connected records.

04 External technical review

Assessment observations and clarifications affected multiple lifecycle records, requiring controlled revisions rather than isolated edits.

Elexes' Involvement

A full software-documentation engagement integrated with assessment response work



SCOPE OF SUPPORT

Elexes developed and refined the complete applicable software documentation package, coordinating the manufacturer's technical inputs with requirements, architecture, detailed design, verification records and software lifecycle controls.

Documentation

Development planning, requirements, architecture, specifications, configuration management, maintenance and release records.

Technical evidence

Verification planning and reporting, traceability, software hazard analysis and risk management.

Assessment support

Cybersecurity records, IEC 62304 checklist updates, external-review clarifications and coordinated controlled revisions.

Methodology

Six linked activities anchored the documentation and review process

01

Baseline and scope

Established the software development-plan baseline and reconciled requirements, architecture and design descriptions.

02

Implementation clarity

Refined regional configurations, calibration behavior, firmware operating states and standalone architecture.

03

Verification evidence

Structured test planning, unit testing, verification cases and links back to software requirements.

04

Cybersecurity architecture

Documented BLE security, AES-128, trust boundaries and protected communication interfaces.

05

Risk and lifecycle controls

Aligned software hazard analysis, risk reporting, maintenance, change control and problem resolution.

06

Assessment and closure

Coordinated review responses, updated affected documents and the IEC 62304 checklist through closure.

IEC 62304 software lifecycle / coherent evidence / controlled technical review

Technical Execution

Requirements, verification, security and quality evidence were developed together

REQUIREMENTS & DESIGN

Elexes refined the SRS, Software Architecture Design Chart and Software Design Specifications. Clarifications addressed regional configurations, calibration-related logic, software operating states and boundaries of the standalone system.

VERIFICATION & TRACEABILITY

The Software Test Plan, Verification Test Case Register, Unit Test Report and Traceability Matrix were developed or refined to connect documented functions with supporting verification evidence.

CYBERSECURITY & SOFTWARE RISK

The cybersecurity evidence described BLE communication, a trust diagram, AES-128 encryption and protected interfaces. Software Hazard Analysis and Risk Management Report documentation were aligned with lifecycle records and identified risk-related controls.

MAINTENANCE & PROBLEM RESOLUTION

Configuration management, release documentation, maintenance planning and software problem-resolution records helped establish a more coherent basis for controlled lifecycle activities.

The Documentation Package

A complete software lifecycle evidence set delivered for the engagement

IEC 62304

SOFTWARE LIFECYCLE EVIDENCE

PLAN	DESIGN	VERIFY	CONTROL
Software Development Plan	Software Requirements Specification	Software Test Plan	Software Hazard Analysis
Configuration Management Plan	Software Architecture Design Chart	Verification Test Case Register	Risk Management Report
Software Maintenance Plan	Software Design Specifications	Software Unit Test Report	Cybersecurity Summary Report
Software Release Notes		Traceability Matrix	IEC 62304 Checklist

All applicable software documents were delivered and finalized, including revisions requested during the technical assessment. The manufacturer confirmed that outstanding observations were resolved and the project was closed.

Assessment & Quality

How Elexes supported TÜV technical review and evidence closure



01

MANUFACTURER INPUTS

Actual architecture, system behavior, firmware and security implementation

02

ELEXES REVISIONS

Requirements, architecture, design, verification, risk and cybersecurity records

03

EXTERNAL REVIEW

Technical clarification and evidence mapping for TÜV assessment

04

CONTROLLED CLOSURE

Updated document baseline, IEC 62304 checklist and resolved observations

Assessment-related observations and applicable revisions were confirmed closed.

Results & Impact

Successfully concluded a Class B IVD CE-marking engagement under IVDR

CE MARKING ACHIEVED

01 Complete software documentation

Lifecycle planning, design, verification documentation, maintenance, configuration management, software risk and cybersecurity records developed and delivered.

02 Review observations resolved

Applicable technical clarifications and document revisions were completed, including IEC 62304 checklist updates.

03 Class B IVD outcome

The manufacturer achieved Class B IVD CE marking under Regulation (EU) 2017/746 (IVDR) following the TÜV-involved assessment.

04 Engagement closed

Final applicable deliverables were completed and outstanding technical review items closed.

Elexes supported the evidence and assessment process; CE marking was achieved by the manufacturer.

Where This Experience Applies

Transferable expertise for other medical-device software and regulatory programs

01 EMBEDDED DEVICE SOFTWARE

IEC 62304 development plans, requirements, architecture, detailed design and lifecycle maintenance for firmware-enabled devices.

02 CONNECTED MEDICAL DEVICES

BLE interfaces, cybersecurity architecture, protected communication, threat-related documentation and software risk traceability.

03 SOFTWARE V&V READINESS

Verification strategies, traceability matrices, unit-test documentation, test-evidence review and technical-file organization.

04 IVDR CE MARKING & CLASS B IVD SUPPORT

Software lifecycle evidence packages and structured documentation for Class B IVD conformity assessment activities under IVDR.

05 NOTIFIED BODY COMMUNICATION

Responding to technical reviewer observations, clause-level evidence mapping and coordinated controlled document revisions.

06 QMS & RISK MANAGEMENT

Alignment of software change control, issue resolution, ISO 13485-related processes and ISO 14971-based risk documentation.

Lessons for Manufacturers

The value of connected lifecycle evidence during external assessment

Start with implementation truth

Document the actual system architecture, regional configuration differences, calibration logic and software operating states.

Build traceability as documentation evolves

Connect requirements, design, verification, software risks and cybersecurity controls throughout development and review.

Integrate quality controls early

Treat configuration management, release records, problem resolution and maintenance as part of the software lifecycle, not as late add-ons.

Respond to reviews as a controlled system

Technical observations may affect multiple documents. Coordinated changes and clear evidence mapping reduce contradictions.

THE CASE STUDY TAKEAWAY

Strong software documentation reflects the actual medical device and makes its lifecycle, risk and security evidence coherent for conformity assessment.

Conclusion

From software implementation to evidence that supports conformity assessment

**A completed CE-marking engagement.
A reusable model for software evidence.**

Elexes supported the manufacturer of a connected point-of-care hemoglobin measurement system through the development and controlled refinement of a comprehensive software lifecycle documentation package. The engagement integrated IEC 62304 documentation, verification evidence, software risk management, cybersecurity and technical assessment support.

Following completion of required revisions and closure of reviewer observations, the manufacturer achieved CE marking for Class B IVD medical device software under Regulation (EU) 2017/746 (IVDR). The engagement was formally closed.

MEDICAL DEVICE REGULATORY • QUALITY • SOFTWARE LIFECYCLE

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