

THE CONTEXT

The standard EN 62304 establishes requirements for the lifecycle of medical software. It covers specification, design, validation, and maintenance, with a focus on risk management. As a harmonized standard, it enables the demonstration of regulatory compliance for medical software within the EU. Thorough technical documentation helps secure the acquisition of the CE marking.

CONSULTING



ISO 13485:2016

BUREAU VERITAS
Certification



MEDICAL SOFTWARE DIAGNOSIS

For any further information:
contact@effinnov.com

THE BENEFITS

- ✓ Securing the acquisition of the CE marking
- ✓ Optimizing deadlines and costs
- ✓ Accessing an independent team of experts

THE OBJECTIVES

- Identifying deviations from normative requirements
- Evaluating the quality and maturity of the software
- Analyzing the level of traceability of design elements
- Defining a compliance action plan

THE INTERLOCUTORS

Project manager
Quality manager
R&D manager

THE WORKFLOW

The mission starts with an analysis of the documentation, searching for evidence of compliance and verifying the level of traceability. The software quality is then assessed through an examination of the source code, analyzing the level of documentation, and tracing the design elements. The duration ranges from 5 to 25 days depending on the size and classification of the software.