EU Health Apps and Medical Device Software Compliance Training Course

11 – 15 January 2027
Rome

AGILE LEADERS
Training Center

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Ref: 1681_226399 **Date:** 11 – 15 January 2027 **Location:** Rome **Fees:** 6500 Euro

Overview

EU Health Apps and Medical Device Software Compliance Training Course is a one-week professional course for digital health, quality and regulatory teams, who leave with an EU MDSW Compliance Decision and Evidence Pack. The course connects intended purpose, qualification, Rule 11 classification, lifecycle controls, clinical evidence, cybersecurity, technical documentation, conformity and post-market governance. Participants document regulatory decisions without treating every health app as a medical device. Agile Leaders Training Center develops practical EU medical device software compliance capability.

Who Should Attend

- Teams responsible for digital health product scope and intended purpose
- Regulatory specialists responsible for qualification and classification decisions
- Quality teams responsible for software lifecycle and risk controls
- Clinical and safety teams responsible for evidence and benefit-risk reasoning
- Software and cybersecurity teams responsible for verification, security and change assessment

The course assumes participants can describe a health software product and its users at work, and leaves out legal advice, medical hardware engineering and coding instruction.

Departments and Industries

The course supports departments that develop, assess or govern health apps and medical device software.

- Digital health and medical technology product teams
- Regulatory affairs and quality management
- Clinical safety, evidence and medical affairs
- Software engineering, cybersecurity and usability
- Healthcare innovation, assurance and procurement

Learning Objectives

By the end of this course, participants will be able to:

- Analyze intended purpose and software qualification boundaries
- Apply Rule 11 and applicable classification rules
- Build lifecycle, quality and risk traceability
- Evaluate clinical, usability and cybersecurity evidence
- Use technical documentation and conformity checkpoints

- Assess post-market signals and software changes

Course Agenda

Day 1: Scope and Intended Purpose

- Health App Function and User Context Map
- MDR and IVDR Scope Decision Tree
- Intended Purpose Statement Builder
- MDCG 2019-11 Qualification Criteria Checklist
- Medical Device Software Boundary Decision Record

Day 2: Classification and Regulatory Pathway

- Annex VIII Implementing Rules Review
- Rule 11 Decision and Harm Impact Matrix
- Software Driving or Influencing a Device Assessment
- Risk Class Rationale and Evidence Log
- Conformity Assessment Pathway Map

Day 3: Lifecycle, Quality and Risk Controls

- Software Lifecycle Process and Responsibility Map
- Quality Management System Interface Matrix
- Software Hazard and Risk Control Traceability
- Usability Task and Use-Error Analysis
- Cybersecurity Threat and Control Register

Day 4: Evidence and Technical Documentation

- Clinical Evaluation and Performance Evidence Plan
- Software Verification and Validation Evidence Matrix
- Requirements-to-Test Traceability Review
- Technical Documentation Structure Checklist
- Release Readiness and Declaration Evidence Gate

Day 5: Post-Market and Change Practice

- Exercise: Qualify and Classify a Health App Scenario
- Exercise: Test Risk, Clinical and Cybersecurity Traceability
- Exercise: Evaluate a Post-Market Signal and Corrective Action
- Exercise: Assess Software Change and Documentation Impact
- Capstone: EU MDSW Compliance Decision and Evidence Pack

Practical Exercises

Suggested activities use patient-monitoring, clinical decision-support and wellness-app scenarios.

- Suggested activity: distinguish a general wellness function from a medical intended purpose
- Suggested activity: document a Rule 11 classification rationale and uncertainty
- Suggested activity: map requirements, hazards, tests and clinical evidence
- Suggested activity: evaluate whether a software change affects the compliance evidence set

FAQs

Who suits EU medical device software compliance training and what does it assume?

EU medical device software compliance training suits product, regulatory, quality, clinical, software and cybersecurity teams. It assumes participants can explain a health software function, intended users and operating context, while excluding legal advice and programming instruction.

How does medical device software compliance differ from general health app development?

Medical device software compliance begins with intended purpose and qualification, then connects classification, lifecycle controls, clinical evidence, technical documentation, conformity and post-market duties. General health app development may focus on features and delivery without establishing a regulated medical purpose.

How does Rule 11 affect EU medical device software classification?

Rule 11 classifies software according to how its information supports diagnostic or therapeutic decisions, physiological monitoring and the potential consequence of an incorrect result. The classification rationale must follow the stated intended purpose and applicable implementing rules.

What evidence belongs in EU MDSW technical documentation?

EU MDSW technical documentation connects intended purpose, requirements, architecture, risk controls, verification and validation, clinical evidence, usability, cybersecurity, labeling, release decisions and post-market planning. The exact evidence depends on product scope, class and conformity pathway.

Conclusion

Participants take back an EU MDSW Compliance Decision and Evidence Pack containing intended-purpose records, qualification and classification rationales, risk traceability, evidence plans, documentation checks and post-market controls. The pack makes software compliance decisions reviewable across product functions. It also helps teams assess changes and evidence gaps before release decisions.