



# Software requirements according to IEC 60601-1 clause 14 3<sup>rd</sup> Ed. and IEC 62304

### Course Description

During the course the requirements in the IEC 60601-1 and the IEC 62304 will be discussed and explained, to provide a detailed understanding of the software safety compliance process.

Gain insight in the characterization of the software requirements aspects of product, risk assessment regard to software verification and validation aspects, determination of applicable product specification and test requirements and learn how to set up the final reporting and Technical Report Forms.

### Learning Objectives

On completion of the training, participants will be able to:

- Understand the software requirement terms and techniques
- Understand the requirements of the applicable (collateral) standards for the product development process
- Understand how to prove the software verification and validation of a medical device
- Understand the requirements for risk assessment and software safety
- Understand the required design and technical documentation

### Examination or testing

During the course cases are used to verify the gained knowledge and skills

### Program overview

- Software systems and classifications
- Software requirements overview and the applicable standards
- How to prove software verification and validation compliance (according to the applicable standards)
- Determine the essential performance
- Data privacy and security

- Determine the applicable analysis and tests
- Cases to perform a risk analysis and software safety tests
- Establish the design and technical documentation records
- Questions & Answers
- Evaluation of the course and Closing

### Who should attend

- Quality Managers
- Anyone responsible for the technical design and compliance of medical software systems

The number of participants is maximized to twelve to provide a stimulating and practical working environment.

### Level

There is no prerequisite for this course; a basic knowledge of basic safety and essential performance of medical electrical equipment is an advantage

### Duration

1 day.

### Training material

Course notes are provided on a USB stick.