

## IEC 60601 ELECTRICAL SAFETY TRAINING FACTSHEET



**Speaker:**

Stefan Staltmayr  
Senior Associate

**Date:** September 24<sup>th</sup> & 26<sup>th</sup> 2024, Online

**Duration:** 8 hours

2x 8:00 – 12:00 AM US Eastern Standard Time  
2x 2:00 - 6:00 PM Central Europe Summer Time

**About the speaker:** Stefan Staltmayr is an industrial engineer with an electrotechnical background and 9 years of experience within the international medical device industry. As a quality technician for production of medical devices he has gained strong knowledge of QMS according to EN ISO 13485. As a product safety engineer for the product safety certification of active and non-active medical devices, Stefan has in-depth experience in preparation and execution of regulatory safety tests and approvals of medical devices and systems in cooperation with external accredited agencies and certification bodies. Due to his work as a product safety engineer Stefan has a profound understanding of IEC 60601 standard series, ISO 14971 risk management aspects, and on IECEE CB-schemes and NRTL test reports approach for medical devices.

### TRAINING OBJECTIVES:

- Gain general understanding of IEC 60601 standards (collateral and particular standards)
- Learn to interpret clauses of IEC 60601
- Insights on electrical safety requirements of medical electrical equipment according to IEC 60601- 1 3.2 Edition

## TRAINING CONTENT:

By attending this training, you will receive in-depth knowledge on the following topics:

- IEC 60601 internationally (market legislation and national differences)
- Explanation of Certification Body (CB) scheme and Nationally Recognized Testing Laboratory (NRTL)
- Short introduction to Risk Management according to ISO 14971 3.0 Edition and Usability according to IEC 60601-1-6 3.2 Edition/ IEC 62366-1 1.1 Edition
- Apply IEC 60601-1 3.2 Edition requirements on medical electrical equipment
- Safety concept and single fault condition
- Focus on clause 8 protection against electrical hazards from medical electrical equipment
- Classification of medical electrical equipment
- Insulation diagram of medical electrical equipment (air clearance and creepage distances)
- Means Of Operator Protection (MOOP) vs. Means Of Patient Protection (MOPP)
- Examples of required tests (leakage current, touch current and dielectric strength)
- Selection of components for list of critical components
- Introduction into IEC 60601-1-2 4.1 Edition

## TRAINING FORMAT:

- Presentation with interactive discussions
- Exercises during the training
- End of training assessment (participants will receive training certificate)

## WHO SHOULD ATTEND:

- Managers and employees working in Quality Assurance or Regulatory Affairs department of medical device manufacturer
- Managers and employees working in Research and Development department of medical device manufacturer
- Technical medical device consultants and associates
- Auditors of medical devices

## PRICE:

EUR 775 incl. course material and certificate

Registration: [education-veranex.talentlms.com](http://education-veranex.talentlms.com)

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