



**Finn Speiermann**  
Senior specialist M. Sc.EE (DTU)

Safety Connected Devices

ID1050

Finn.Speiermann@medicologic.com

**medicologic**<sup>®</sup>

Medical Device Development

Medicologic A/S  
Arne Jacobsens Alle 17  
Ørestad City  
DK-2300 Copenhagen  
Denmark

(+45) 48 24 51 13  
contact@medicologic.dk  
www.medicologic.dk

## Competences

- Medical Device and IVD compliance
- Risk analysis, FMEA, FMECA
- Device safety and security standard specialist
- EMC design/test at board & system level. EMC standards & compliance.
- Signal analysis / processing
- RFID, NFC
- Analog & digital filters
- Communication and network solutions, RS232/RS485/RS422, USB, Ethernet, I2C, SPI, CAN
- Wireless solutions incl WiFi, Bluetooth, BLE. RED compliance.

## Standards

Extensive knowledge in:

- **UL2900-1 and UL2900-2-1**  
[Security for network connected devices]
- **AAMI TIR57**  
[Medical device security – risk management]
- **IEC61010, IEC62368**  
[Device safety]
- **IEC60601**  
[Safety / Medical Device]
- **ISO14971, Risk analysis**  
[Risk management, FMEA, FMECA]

## References

### **Medicologic A/S (present)**

**Senior Consultant**  
Safety Connected Devices

### **Prevas A/S (present)**

**Senior Specialist**  
Safety Medical Devices

### **N/N medical device manufacturer**

Medical device HW technical lead. Device development, device maintenance and production test systems. EN/IEC 60601 route to compliance. Support to CE marking, FDA, and FCC approval

### **N/N medical device manufacturer**

IEC61010 conformance support for IVD and IEC14971 risk analysis support.

### **N/N major medical device manufacturer**

Medical device, IEC60601 and UL2900-1/UL2900-2-1 conformance.

## Key results

Key IEC61010 / 60610 compliance specialist on numerous IVD and medical device projects

Decades of experience in Ensuring Radio Emission Directive and FCC radio compliance on various devices, IVD, medical and others.

Assisting on security risk compliance for several network connected medical devices.

## Personal Characteristics

Experienced medical and IVD device compliance specialist within the areas HW solutions, technical lead, hardware design, EMC, medical devices, risk analysis, safety, and security. Has the ability to focus on the important details while still maintaining the technical overview. A good communicator which can bridge among the various technical disciplines in a project.

Specialty: Medical device development, IEC60601 compliance, risk management.

### **N/N major medical device manufacturer**

Medical device, IEC60601, and AAMI TIR57 compliance, RED compliance. Electronics tech lead.

### **N/N medical device manufacturer**

IEC60601, ISO14971 compliance for medical device.