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# CONNECTED TO THE FUTURE.

TÜV Rheinland Services in the Medical and Healthcare Sector.

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 **TÜVRheinland®**  
Precisely Right.

# TÜV Rheinland Services in the Medical and Healthcare Sector.

## Main topics

- Evaluation of Wireless Technologies
- Evaluation of Cyber Security
- Testing and Certification of Medical Devices

## Medical Approvals and International Market

### Access Services

- The EU directives on Medical Devices (93/42/EEC), Active Implantable Medical Devices (90/385/EEC) and In-Vitro-Diagnostics Medical Devices (98/79/EC)
- CMDCAS (Canada), PMD Act (Japan), TCP (Taiwan), INMETRO (Brazil)
- New Medical Device Single Audit Program (MDSAP) for USA, Canada, Brazil, Australia and Japan
- Market requirements research
- Support for developing new markets
- Specific market approvals
- Medical Devices according to CB (IECEE), USA/CAN testing approval (NRTL) cTUVus, A2LA (US)
- "GM Mark" Medical Device Certification
- Wheelchairs, rollators, scoot mobiles, medical beds and hoists
- Blood glucose monitors and pen injectors
- Medical lighting/lamps; Light levels and spectral distribution; personal eye protection

### Quality Management certification according to

- EN ISO 13485 for medical device manufacturers
- EN ISO 15378 for manufacturers of primary packaging materials for medicinal products

### Testing and certification of

- All medical electrical equipment according to IEC/EN 60601-1, 60601-1-x, 60601-2-x
- Wireless medical devices (Wi-Fi, Bluetooth, Zigbee)
- Biocompatibility, biomaterials, tissue engineering, haemocompatibility, cytotoxicity, verification of effectiveness of disinfection, sterilization and cleaning processes
- Measurement/control and Laboratory use equipment according to EN 61010-1, 61010-2-x

### Cyber Security services

- Cyber Security advice regarding international Cyber Security Guidelines
- Device Security Risk Analysis
- Software Application Security Assessments
- SDLC Assessments and Implementation
- Security Management Programs
- Legacy Devices Advice
- Penetration and Fuzz Testing
- Static Code Analysis
- Cloud Security Assessments
- Threat-Controls Matrix

### Specialty Media/Training/TÜV Rheinland as an employer

## Test mark example



Safety  
Regular  
Production  
Surveillance



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## Contact

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