Governance & Compliance – Medical Devices Market Services

Mission

Our **mission** is to supply consulting services to Customers for the evolution and certification of the Medical Devices and for supporting Customers in the definition and implementation of company growing plans

Services

- Reengineering of **System Requirements Specifications** and **Software Requirements Specifications**.
- **Hazard identification and risk analysis** on safety-relevant medical device products.
- **Hazard identification and risk analysis** on software embedded in the medical device.
- Definition of the **safety control measures**.
- Medical device **Security assessment** and development of the Security Technical Report according to IEC 80001.
- Software items **A/B/C classification** according to IEC 62304.
- Development of the **Risk Management Reports** for the medical device and for the embedded software.

Competences

- **Medical device and software Risk Management**: ISO 14971, IEC TIR-80002, IEC 80001, ISO/IEC 31010, ICH Q9.
- **Medical device software lifecycle**: IEC 62304, 21 CFR Part 11, EC GMP Annex 11, ISPE GAMP5.
- **Safety Analyses**: HAZOP, FMEA, FMECA, FTA.
- **Medical device lifecycle**: IEC 60601, IEC 61010, IEC 61508, IEC 62366.
- **Quality Management System**: ISO 13485, ISO 9001.

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