QUALITY MANAGEMENT

All processes in development and production comply with high quality standards, especially the requirements for medical devices. Next to the certifications EN ISO 9001 and 13485 we are audited by FDA as „Manufacturer of Medical Devices“.

RESEARCH AND DEVELOPMENT

- Planning and documentation of the whole development process compliant to actual standards (Design History File)
- Implementation of software lifecycle management processes according to DIN EN 62304:2007-03
- Validation of processes and devices
- Verification of climate, storage, vibration and transportation conditions

Specific quality requirements will be fixed in quality assurance agreements in collaboration with our costumers.

PRODUCTION

- Process monitoring, error tracking, CAPA, 8D
  (Device History Record)
- Implementation of test strategies
- Development and realization of complex test equipment
- Change management
- Supplier monitoring