



# Industry Profile Medical Technology



**Konzept**  
Informationssysteme GmbH



## **Innovation and technology: The progress that saves lives**

Medical technology is a dynamically growing sector that is characterised by its high level of innovation and technology density. It has a decisive role within modern healthcare and contributes significantly to its efficiency. Increasingly, there are challenges for companies: strict government regulations, increasing complexity and high costs characterise the often lengthy development process for new medical technology products.

## **Safety and performance are key aspects**

Medical devices require comprehensive technical and clinical testing before they can be further trialled and ultimately used on patients. The protection of the patient and the patient's well-being have the highest priority. For the use of technical products and systems, this results in them being subject to maximum safety requirements, tests and a strict quality management system.

## **Scope of Services**

- System and software development in accordance with IEC 62304
- Development of operating concepts for medical technology devices
- Prototype development
- Requirements engineering

## **Professional support at any stage**

With our years of expertise in medical technology and the development of complex systems, we offer you comprehensive support in all phases of your project. As a qualified partner, we provide you with support throughout the entire development process in order to realise optimal solutions together.



## Specific Project Experience

- Touch interface product development for users involving user profiles in the lab environment
- Support for use case and stakeholder analyses for product optimization geared to market requirements
- Interfacing / communication with other components of the overall system
- Support for resource optimization in runtime environments
- Preparation and realization of component and system tests
- Product development for minimally invasive surgery using a robot arm
- Low-level software development at microcontroller level
- Implementation and integration of boot loaders
- Runtime optimization
- Working out safety maintenance concepts
- Implementation of various interface protocols
- Validation of computer systems in the biopharmaceutical sector according to GMP
- Software development for minimally invasive surgery

## Systems Engineering

- Requirements management at system level
- System architecture and design
- Analysis and consulting for the selection of software components for runtime environments

## Softwareentwicklung

- Software requirements management
- Software architecture
- Software module design and implementation

### Norms and Standards

V-Model	IEC 62304
GMP	GAMP 5
ISO 13485	

## Verifikation und Validierung

- Preparation of module and unit testing
- Unit- / integration, system tests and test management
- Preparation of the test documentation for module, integration and system tests
- Creating automated test sequences at module and sub-integration levels
- Validation
  - System requirements
  - Software requirements

## Tool-Erfahrungen (Kurzauszug)

- Enterprise Architect
- Qt creator, qt quick and qt widget
- qt QML, C, C++
- MariaDB
- C#, WPF, .NET
- GIT
- Doxygen
- Jira, confluence, Helix ALM
- alfresco
- vera++, cppcheck
- Yocto - ubuntu
- Various microcontroller

## Unterstützungsprozesse

- Project management
- Quality assurance
- Configuration management for subcomponents
- Problem and change management
- Documentation