

Tomorrow's Healthcare Technology

www.itk-engineering.de

Medical Systems Engineering

Reliable. Built for approval. Forward-thinking.



The transformation of medical engineering

DIGITAL. SECURE. CONNECTED.

Connected medical devices, medical apps, paperless clinical trials, cloud-based patient solutions – the digital transformation is in full swing in the medical and healthcare industry. Competitive pressure is high. Developments have to come fast. Systems must be user-friendly, yet secure. We have been rising to these challenges as an ISO 13485- and ISO 27001-certified engineering partner since 1994. Capitalizing on our cross-industry experience, we combine software and systems engineering, device connectivity and cyber security to shape the things to come in digital health.



What sets us apart

- 25 years of experience in standards-compliant software and system development for medical devices
- Complete OEM product developments
- White box business model
- Software, hardware und mechanics from a single source
- Experience in robotics projects since 1996
- Embedded expertise
- Medical consulting born of experience
- Network of industry and research partners



ISO 9001



EN ISO 13485



ISO 27001



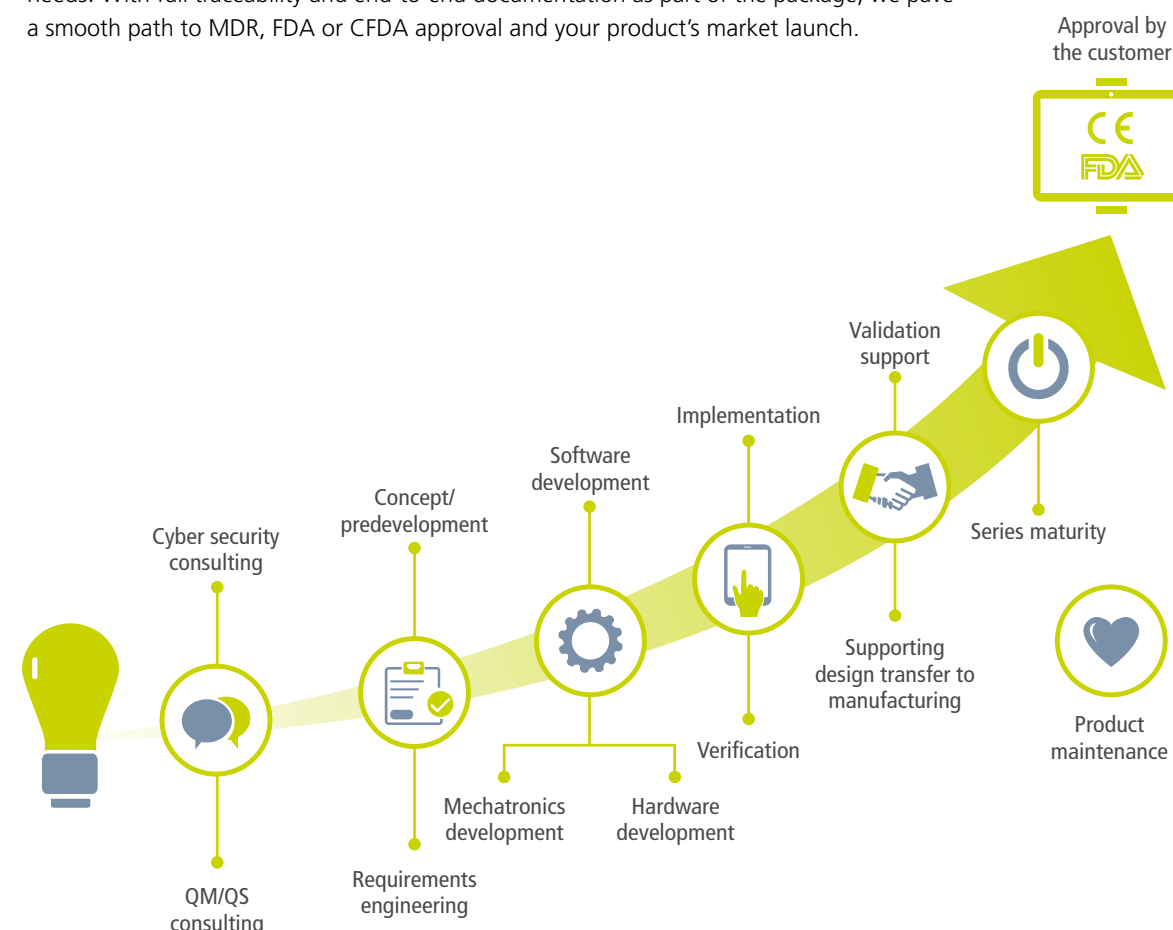
EN ISO 13485:2016
certified

From the inception idea to the approved product



TAILOR-MADE. BUILT FOR APPROVAL.
ON SCHEDULE.

Supporting you throughout the development process, from the inception idea to the product and beyond, we help guide your ideas to real-world success. To this end, we develop full-fledged systems with all the software and hardware and mechanical design tailored to your needs. With full traceability and end-to-end documentation as part of the package, we pave a smooth path to MDR, FDA or CFDA approval and your product's market launch.



Tailor-made systems out of one hand



INTERDISCIPLINARY. RELIABLE.
FROM A SINGLE SOURCE.

Medical device, robot, virtual OR or medical cloud – whatever innovative solution you want to put into practice, we make the most of our methods, industry expertise, and firm grasp of trends and challenges to help you do it. What sets us apart: Count on our interdisciplinary teams to deliver turnkey systems from a single source. If you wish, we can handle quality assurance throughout the process, from the drawing board to the manufacturing floor. Our proven and flexible manufacturing partners help us deliver on our performance promise.



Your advantages

- Holistic engineering
- Interdisciplinary teamwork
- Standards-compliant development
- Flexible manufacturing

Our engineering services at a glance

REQUIREMENTS & SYSTEMS ENGINEERING

- Derive stakeholder requirements
- Develop manageable user stories
- Create proof of concepts
- Derive system requirements
- System architecture
- Design subsystems
- Standards-compliant documentation

SOFTWARE



- Software architecture
- Software design
- Implementation
- Verification and integration
- Tool and/or SOUP validation
- Algorithms, AI, image processing
- User interfaces & user experience

HARDWARE



- Verified building blocks
- Medically safe industrial interfaces
- Embedded controllers and Linux modules
- Connectivity and remote control
- Battery management

MECHANICS



- Design and dimensioning of mechanical precision parts
- Housing, supporting structure, cooling, display integration
- Prototyping
- Production-ready design for manufacturability
- Robotics and assistance systems

MANUFACTURING



- Flexible business model – you manufacture it or have us build it with our flexible partners
- Proven, ISO 13485-certified manufacturing partners
- Manufacturer-independent
- Test bench development

MAINTENANCE



- Lifecycle management
- Product updates
- Maintenance & support

QUALITY ASSURANCE

- EN ISO 13485:2016 QM system
- IEC 62366-1:2015 usability engineering
- ISO 14971:2013 risk management
- IEC 62304:2016+A1:2015 software lifecycle
- MDR:2017, FDA, IVDR regulatory affairs
- DIN EN 60601-1:2013 medical basic safety for medical electrical equipment device safety
- IEC 80001:2010 security
- IEC 61508:2010 safety

One-stop supplier for Digital Health solutions



BUILT FOR APPROVAL. SUCCESSFUL. FAST.

When we set out to develop digital health solutions, mobile medical apps and the like, we do it with a passion for innovation, laser-like focus on results, and lean but standards-compliant processes. Cyber security, data protection, and regulatory issues are on our minds from day one so nothing will deter your successful market launch.

Our services at a glance



**Medical apps and
mobile applications**



Cyber security check



**Wearables and
personal health devices**



**Cloud-based
patient solutions**



**Secure frontend and
backend development**



Data analytics



**Connectivity for
medical devices**



**Consulting regarding regulatory
aspects and building new
business models**



**User interfaces
User experience**

Your advantages

- Shorter time-to-market for your innovations
- Cyber security by concept
- Data privacy by design
- Patient empowerment
- Open and cloud agnostic



Smart robot-supported assistance systems



SECURE. INTERACTIVE. ASSISTIVE.

Robotics have become indispensable in medical engineering. Our interdisciplinary team of control engineers, software developers, system architects and mechatronics experts implements smart and user-friendly assistance systems. These innovations are able to extend the range of treatments available to doctors, surgeons and care personnel and to increase the precision of procedures

Our services at a glance



CONTROL SYSTEMS

- Kinematics, dynamics and motion planning
- Motor control and sensor technology
- Embedded and real-time systems
- Navigation for mobile robot systems



„INTELLIGENCE“

- Image processing
- Cognition, autonomy



HUMAN-ROBOT INTERACTION

- Collaborative operating concepts
- User interfaces, dialog systems
- Functional safety
- Teleoperation, haptic feedback



CONNECTIVITY

- Remote diagnostics and maintenance
- Cloud connectivity, cyber security



SIMULATORS, VIRTUAL AND AUGMENTED REALITY

- Training and support for service applications



PROTOTYPING



Your advantages

- Interdisciplinary team for your specialty applications
- Rapid evaluation of your ideas
- Accelerated time-to-market for your innovations
- Documentation ready for approval

Cyber security

for peace of mind

HOLISTIC. SECURE. CROSS-DOMAIN.



Cyber security is not some voluntary exercise; it is a non-negotiable essential of the healthcare system's digital transformation. Connected medical devices on the Internet of Medical Things and artificial intelligence (AI) present many unprecedented possibilities, but they also offer many more points of ingress and egress for cyberattacks. Building on our expertise in functional safety and cyber security, we make sure your medical product is protected. Our experts team up with yours to develop a holistic, security-by-design concept to guard your systems against cyberattacks.

Your advantages

- Minimize risk
- Reveal unconsidered attack vectors
- Rule out unexpected bugs
- Set up security engineering process

Our engineering services at a glance

STAGE 1: TAILOR-MADE SECURITY CONCEPT



Security risk analysis

Requirements, threats und vulnerabilities in relation to risk analysis according to ISO 14971 including safety risks.



Choice and parametrization

of controls and cryptographic algorithms.



Security concepts

e.g. based on NIST cyber security framework: protocol design, secure SW architecture, secure HW design.



Based on 25 years of engineering experience

in a highly regulated healthcare environment (MDR/IVDR, FDA Guidance Papers, MBetreibV, AAMI TIR 57, IEC 62443, IEC 60606-1, IEC 80001-1) and in the automotive industry, 10 years embedded security track-record.

STAGE 2: STANDARDS-COMPLIANT IMPLEMENTATION OF YOUR SECURITY CONCEPT



Secure Coding

in our software engineering service.



Based on our SEP

Security Engineering Process and ISO-13485:2016- and ISO-27001-Certification.



Code-Reviews

of in-house and third party software based on secure coding guidelines.



Based on 25 years of engineering experience

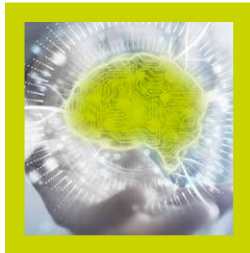
in development of safety-critical medical devices & software and robotic telemanipulation systems.

STAGE 3: SECURITY TESTING



- Security concept reviews
- Grey box and White box penetration testing: manual and automated tests at reasonable effort
- Protocol validation and verification
- CVE based security scans
- Fuzzing
- Separate team from implementation team (team red / team blue approach)

Health data analytics – More than merely algorithms



**FORWARD-THINKING. SECURE.
BUILT FOR APPROVAL.**

These days, AI-assisted medical technology is science fact. AI is seeing widespread use in research, diagnostics, drug development and image processing. The machine learning code is but one small piece of the larger puzzle. Our wide-ranging expertise covers every aspect of the AI ecosystem. Let us put these skills to work for you and help you make the most of your data.

Our services at a glance



CONSULTING

Explore the possibilities and limits of technologies, ideation and incubation.



DATA PROCESSING

Make your datasets usable.



SELECT THE RIGHT METHODS AND ALGORITHMS

for the given application and quality.



OPTIMIZE PERFORMANCE

for deployment in embedded devices.



CONDUCT FEASIBILITY STUDIES AND ASSESS BENEFITS

for alternative approaches.

Your advantages

- Special AI team of engineers and software developers
- A diverse AI skill-set
- Field-tested and with a solid science background

Medical consulting born of experience



HANDS-ON. HOLISTIC. SUPPORTIVE.

Standards, rules, regulations: The medical industry certainly has plenty of challenges in store for new medical devices. As a certified partner, we have the know-how to rise to the occasion. We accompany you from the beginning to the approval with this motto in mind: What we advise, we can also provide.

Our services at a glance



REGULATORY CONSULTING: MDR, IVDR, FDA



RISK MANAGEMENT SUPPORT- ACCORDING TO ISO 14971:2013

- Determine risk policy and risk acceptance
- Conduct FTA to assess system architecture
- Document and link to development artifacts



CYBER SECURITY CONSULTING

- Analyze threats and vulnerability analysis for medical devices
- Define security concepts and protective measures
- Run security tests
- Advise on security engineering process

Your advantages

- MDR readiness
- Consulting rooted in real-world experience
- Methodically accompanied requirements and usability engineering
- Optimized risk file



USABILITY ENGINEERING SUPPORT ACCORDING TO IEC 62366-1:2015

- Determine use cases from the user's perspective
- Identify and minimize risks for the user



PRACTICALLY-PROVEN SOFTWARE DEVELOPMENT CONSULTING COMPLIANT TO IEC 62304:2016 UND A1:2015

- Efficient implementation of standards, including templates
- Tool support



QUALITY MANAGEMENT CONSULTING COMPLIANT TO ISO 13485:2016

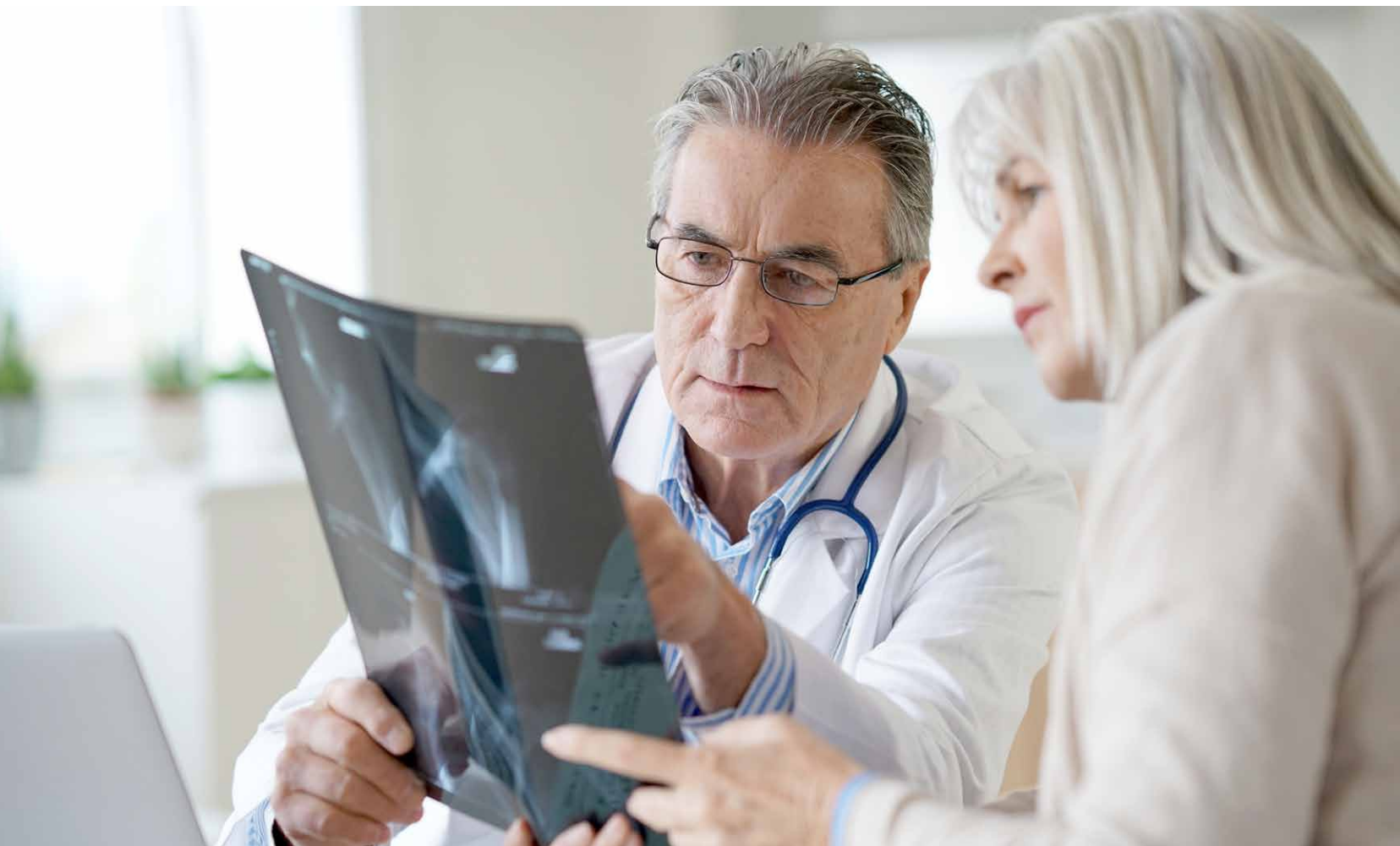
- Conduct ISO 13485:2012 vs. ISO 13485:2016 gap analyses
- SPICE medical evaluation model
- Practical implementation with templates and artifacts

People first



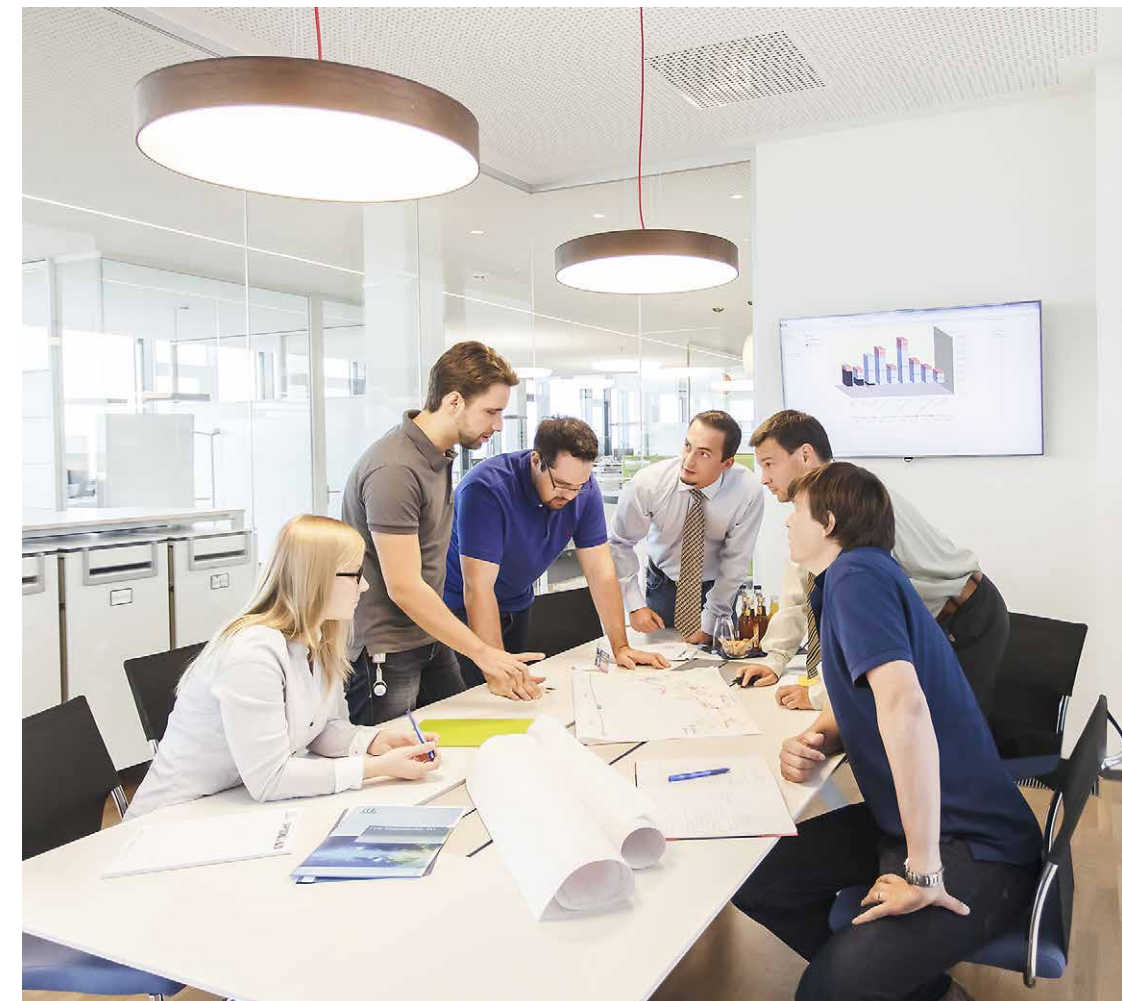
INDIVIDUAL. PREVENTIVE.
PATIENT-CENTERED.

Thanks to the digital transformation and an increasingly connected network of players, it's goodbye volume-based medical management and hello value-based healthcare. The age of the empowered patient and personalized medicine is dawning as the individual gains access to information, greater influence and decision-making options.



A PARTNERSHIP FOR TOMORROW'S HEALTHCARE TECH TODAY

Let us join forces to tap the power of new technologies and develop secure, connected healthcare solutions with smart, patient-centric functions. This way, we can make the most of technology to shape the transition to personalized medicine with a human touch.





ITK Engineering

Stability, reliability and methodological expertise – this is what we have stood for since our founding in 1994. At all times, our customers have benefitted from our dedicated multi-industry know-how, especially in the fields of control systems design and model-based design. Customers can count on us – from conception to deployment, we cover the entire development process.

Our areas of expertise include:

- Software development
- Hardware development
- Electrical & electronic systems
- System integration
- Software as a product
- Turnkey systems
- Customer specific development
- Technical consulting
- Seminars
- Quality assurance

The satisfaction of each of our partners and mutually respectful cooperation shape our corporate philosophy, in which four values are firmly anchored: Read more about this on the web.

Visit our website to find out how we can help you with your digitalization strategy: [medical.itk-engineering.com](https://www.medical.itk-engineering.com)

We look forward to advise you personally.

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Founded in 1994 –
Branch offices throughout
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worldwide.

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