

EXPERTISE



## EXPERTISE – DEVELOPMENT

### Development

In developing medical technology devices, components and partial solutions, we cooperate with you on the basis of defined interfaces.

Development processes and structured working methods support our interdisciplinary teams during development. With the aid of these processes, we are guaranteed to meet the requirements of worldwide markets.

The development process is supported by the use of modern, high-performance tools (e.g. system modelling, automated testing, document and risk management).

In dialogue with you, we work in accordance with an adapted, phase-oriented development process based on the V-Model.

In the pre-development phase, we offer you:

- = Requirements elicitation and analyses
- = Feasibility analyses (feasibility studies, proof of concepts)
- = Detailed investigations
- = System concepts
- = Technology developments
- = Simulations (e.g. user areas)

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### Software development

To ensure that your product is developed quickly and safely, we use efficient software development environments and high-performance programming languages (with a focus on C/C++ and C#).

We develop the following for you:

- = PC-based software (including applications supported by databases)
- = Embedded software and firmware
- = User interfaces (including their simulation), taking into account the applicable standards (e.g. DIN EN 62304) and preparation of the necessary documentation (software architecture, software FMECA)

Software tools:

- = Magicdraw (UML/SysML)
  - = System modelling
  - = Requirements management
  - = Test planning
  - = Software design
  - = Traceability
- = IAR Workbench (embedded software development)
- = Microsoft Visual Studio (application development)
- = Rational Test RealTime (software unit level testing)
- = CPU Test (software unit level testing)
- = Crystal Revs, PCLint (static code analysis)
- = Surround SCM (configuration management)
- = Seapine Test Track Pro (issue and bug tracking)

Programming languages:

- = C / C++ / EC++
- = C#
- = HTML, DHTML, Flash
- = Java
- = Visual Basic
- = Delphi
- = Perl
- = PHP
- = SPS
- = VBA
- = VBScript
- = HP VEE / Agilent VEE
- = Assembler
- = LabView

Operating systems:

- = QNX Neutrino
- = Linux (desktop and embedded)
- = Windows (desktop and embedded)
- = Android
- = Apple IOS

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### Electronics development

We develop electronics for you, from the initial idea up to series-production readiness:

- = Development of analogue and digital circuits
- = Circuit simulation
- = Creation of layout
- = Consideration of “Design for X”  
(e.g. cost, manufacturing, testability)
- = Preparation of the necessary documentation  
(e.g. isolation diagram, parts list, circuit description, electronics concept/architecture)
- = Experience in using a wide variety of microcontrollers, 8–32 bit, wide range of architectures and manufacturers
- = Experience in using embedded PCs
- = Supervision of approval tests (e.g. EMC test laboratory)
- = Execution of functional/performance tests
- = Construction of prototypes in-house with various options for testing (test environments for in-circuit tests, functional tests and climatic tests)

Microcontrollers, including:

- = NEC
- = TI
- = ST
- = ARM
- = Atmel
- = Renesas
- = Infineon
- = Cypress
- = Microchip
- = Zilog

Tools:

- = Altium Designer (circuit diagram development/layout)
- = LT spice (circuit simulation)
- = SIMetrix (circuit simulation)
- = Minitab (statistics software)

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### Mechanics development

We develop the functional mechanics for your medical technology systems or modules with the aid of state-of-the-art 3D design software. Using suitable tool interfaces, electronic CAD models are imported in the early phases of development to ensure that components are integrated as efficiently and safely as possible during the development of devices.

We develop functional mechanics for you using the latest tools, such as Solid Works for creating 3D models. During the course of the project, we create rapid prototyping samples.

We implement the design requirements for the housing or functional components in accordance with your specifications. If necessary, we are also happy to collaborate with long-standing industrial design partners or a design agency of your choice.

We offer you:

- = The development of complex, multi-functional components, modules and systems combining:
  - = Mechanics
  - = Electromechanics
  - = Fluidics
  - = Pneumatics

And the integration of:

- = Kinematics
- = Actuators and sensors
- = Optical and pneumatic components
  
- = Component design in metal, plastic and other functional materials
- = Design that is suited to processing and the materials used, particularly in plastic; simulation of component behaviour
- = Selection of suitable plastics, taking into account the specific requirements of medical technology
- = Stipulation of suitable production processes as well as coating and finishing processes, taking into account technical and financial aspects
- = Implementation of optimum solutions, depending on quantities in series production and production requirements
- = Coordination and technical consultation with tool manufacturers and mass producers in the case of tool-based production components
- = Optimisation of existing solutions in terms of production costs or product reliability
- = FEM calculations
- = Simulations and animations
  
- = Tools
  - = 3D CAD Solid works

## EXPERTISE – DEVELOPMENT

### Project management

You have one central contact at our company: the project manager. Our professional project management saves you time and money. A customer-specific reporting system keeps you transparently and promptly informed about the current status of the project (costs, schedule, technology etc.).

- = Review meetings
- = Basis for planning, e.g.:
  - = Project Management Organisation (PMO)
  - = Index List (IX)
  - = Project Plan (PP)
  - = Design, Development and Quality Plan (DDQP)
- = Configuration management

Tools:

- = MS Project
- = Seapine Surround SCM
- = UKIS document management system (Hauk&Sasko)
- = Minitab (statistics software)

### Systems engineering

Complex systems are modelled on the basis of the standardised graphical modelling language SysML. This supports the analysis, design and testing of complex systems. It also allows system information to be communicated between different stakeholders in a uniform manner.

Tools:

- = MagicDraw

## EXPERTISE – QUALITY MANAGEMENT

### Quality management to accompany development

Our quality management department provides you with a capable contact for regulatory and normative issues as well as in the field of risk management.

We support and accompany you with:

- = Preparation of a risk management plan in accordance with DIN EN ISO 14971
- = Research into the applicable standards and basic regulatory conditions
- = Definition of criteria for compliance with the basic requirements in accordance with Annex 1 of Directive 93/42/EEC
- = Preparation of technical documentation in accordance with standards, as specified by Directive 93/42/EEC
- = Setting up of the product file
- = Setting up of the risk management file
- = Approval of medical devices in Europe and internationally (e.g. CE marking for medical devices, MDD, IVD, AIMD, FDA 510k or PMA, FDA de novo)

Tools:

- = FMEA 7 for medical devices (performance of FMEAs and risk analyses)
- = UKIS document management system

## EXPERTISE – PRODUCTION

### Production

As a certified provider of production services with a focus on assembly and inspection, we ensure that your devices and/or components are delivered on time.

We see ourselves as a full-service manufacturer for small to medium-sized batches – from procurement and assembly to final inspection and dispatch.

We implement the principles of GMP, which form part of the international standard for the production of medical devices.

### Transfer to series production

We assemble small and medium-sized batches ourselves and entrust larger quantities to selected cooperation partners or transfer them to your production department.

- = Selection of production technologies
- = Materials selection and qualification
- = Initial sample testing
- = Supplier management and qualification
- = Process qualification and validation (IQ, OQ, PQ)

### Series production

- = Global materials procurement
- = Incoming goods inspection
- = Assembly
  - = Module assembly
  - = Device assembly
- = Preliminary and final inspection
  - = Manual
  - = Automatic
- = Logistics
  - = Logistics concepts
  - = Variable batch sizes for retrieval
  - = Customer-specific packaging and dispatch
- = Quality
  - = Error tracking across processes
  - = Process and quality monitoring
  - = Traceability
  - = Documentation (device history record)
  - = FDA-registered
  - = CSA-controlled



## ADDITIONAL SERVICES

### Consultation and approval support

We support and accompany you with:

- = The classification of the medical device in accordance with Annex 9 of Directive 93/42/EEC
- = The preparation of a risk management plan for your medical device in accordance with DIN EN ISO 14971
- = The preparation of technical documentation in accordance with standards, as specified by Directive 93/42/EEC
  - = Setting up of the product file
  - = Setting up of the risk management file
- = Approval of medical devices in Europe and internationally (e.g. CE marking for medical devices, MDD, IVD, AIMD, FDA 510k or PMA, FDA de novo)
- = Setting up and further development of your management system in accordance with ISO 13485 and/or 9001 (QM handbook, processes and procedural instructions etc.)
- = FMEA and risk analysis
- = Clinical studies/evaluations = technical due diligence

### After-sales service

We also take care of providing after-sales product support for you.

- = Repair service
- = Fault diagnosis
- = Functional and system tests
- = Provision of spare parts
- = Stocking of spare parts
- = Obsolete component management
- = Logistics
- = Product maintenance
  - = Update
  - = Upgrade
  - = Redesign

# PROJECT REFERENCES

## Examples of projects

## Project content

	Development			Production	Certification	
	Software	Electronics	Mechanics		CE	FDA
Active implantable devices	■	■	■		■*	■*
Anaesthetic machines		■	■	■	■	
Blood gas analysis	■	■	■	■	■	■
Blood donor systems	■	■	■		■	■
Blood glucose meters (home care, point of care, CGM)	■	■	■		■	■
Feeding pumps (parenteral/enteral)	■	■	■		■	■
Fill level monitoring and control systems	■	■	■	■	■	
Gas analysis/dosage and monitoring	■	■	■	■	■	■
Infusion/medication pumps	■	■	■		■	
Inhalers and nebulisers	■	■	■	■	■	■
Laboratory test systems for test strips	■	■	■	■		
Combined systems for production of artificial nutrition	■	■	■	■	■	
Oxygen supply	■	■	■	■	■	
Monitoring of vital parameters (ECG, SPO2, etc.)	■	■	■	■	■	■

\* Approval preparation

## CONTACT



We would be happy to show you what we can do and to provide references at a personal meeting.

Please get in touch.

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