Expertise
under one roof

Electronic products and solutions for your medical devices

siemens.com/electronicsystems
“The medical industry is a highly complex and sensitive field – superior quality is an absolute must-have to ensure the patients’ well-being. Our customers are operating in a dynamic industry with rapid innovation cycles.

To prevail in this environment, our clients must always be one step ahead of the fray and deliver cutting-edge excellence while also managing ever greater cost pressure.

How can they master this complex set of challenges? With a partner who offers comprehensive, one-stop expert solutions.”

Frank Bartels
Siemens Healthineers
Our expertise – at your service

With all our expertise housed under one roof, we are your one-stop shop for medical technology solutions. This is how you benefit:

We drive innovative solutions at the very pulse of your fast-evolving market. Our agile responsiveness gives you a sharp competitive edge.

Our efficiency gains are your cost savings. Cost optimization is our priority from the outset, which is why we are continuously streamlining and standardizing our processes, eliminating expensive fixes down the road. Our comprehensive attitude towards cost also extends to aftersales, minimizing your total cost of ownership.

Partake of our quality culture and long years of experience at Siemens Healthineers. Our quality management system, which is certified according to international standards, makes us your ideal partner for successful medical technology.

With us, you will experience a genuine, long-term partnership: We will cooperate closely to elaborate your ideas across all stages of the value chain – from concept to aftersales.

Whatever your individual requirements are – electronic assemblies, subsystems, or ready-to-use devices – thanks to our vast experience, we have the capabilities to configure your solution specifically to your needs.

You want to bring your innovation to market before your competitors do, and you are committed to delivering top-notch quality, flexibility, and moderate cost – knowing that you have the full support of a reliable partner?

Then let’s start a conversation about how we can build your solution.
Electronic products and solutions – excellence from concept to roll-out

Project management

Concept & Development
Customer-specific consulting and requirements analysis, solution concept, system architecture, functional specifications, design specification, hardware design, FPGA design, software design

Industrialization
Component engineering, PCB design, prototyping, test system development, new product launches

Aftersales
Lifecycle analyses, obsolescence management and replacement parts, repair services

Production & Logistics
Electronic assemblies, subsystems and end products, customer-specific logistics, global material management

Thanks to our one-stop solutions, you will benefit from our synergies, cost efficiencies, and vigorous quality standards and you can rest assured that your final product will be exactly what you need.

Certifications:
Management system standards
- ISO 13485 Quality Management System for the Design and Manufacture of Medical Devices
- ISO 9001 Quality Management Systems
- Directive 93/42/EEC Medical Devices, Annex II
- ISO 14001 Environmental Management Systems
- ISO 27001 Information Security Management Systems

Essential product standards
- IEC 60601 ff. Safety Standards for Medical Electrical Equipment
- ISO 14971 Application of Risk Management to Medical Devices
- IEC 62304 Medical Device Software
- IPC-A-610 Acceptability of Electronic Assemblies
Experts for concept and development

Together, we will translate your ideas into a final product, closely cooperating along the entire development process from concept to design realization and taking into account all applicable medical regulations and the current state of the art. Our solutions are focused on functional safety. Our professional project management helps keep you within your time and cost budget.

System concept and system architecture
In this stage, we will...
• consult you and conduct a comprehensive requirements analysis
• create a complete system design and define system architecture
• set functional specifications
• set design specifications for hardware, software, and mechanical components

Here’s how you benefit:
Whether we’re building on your existing design specifications or start with your idea to create a brand-new system— we have the infrastructure to handle your requirements. Based on your ideas, we will develop a solution that is perfectly tailored to your needs.

Hardware design
In this stage, we will...
• provide analog, digital, and mixed signal design all the way to high-performance, high-frequency applications
• offer in-depth technical expertise in all standard communication interfaces (e.g. CAN, GBit-LAN, Bluetooth, PCIe, Profinet)
• use measurement instrumentation and analytic simulations to conduct characterizations

FPGA design
In this stage, we will...
• share our comprehensive know-how for complex FPGA design technology and methodology
• implement high-speed applications, system-on-chip-solutions, and standard logic
• use pretested IP cores
• conduct functional verification of the FPGA design
• ensure regulatory compliance in terms of FPGA design and configuration management

Here’s how you benefit:
Our expertise and broad range gives you the powerful hardware you need to drive your solutions.

Software design – embedded software
In this stage, we will...
• develop embedded software for assemblies to control a wide range of system functions, communications software, or other applications, also in terms of safety
• adapt and integrate board support packages and develop device drivers based on Linux and QNX
• integrate communication protocol stacks such as CANOpen, PRFINET/PROFISAFE
• integrate an embedded middleware platform as a powerful basis to develop control applications

Here’s how you benefit:
Our in-house software developments are tailor-made for your system and comply with all mandatory safety requirements.

Expertise under one roof
Experts for industrialization

In this step, we optimize the results we gained during the development stage for manufacturability and get your solution ready for serial production.

Component engineering
In this stage, we will...
• help you make the best selection of components for new designs and re-designs
• use our component database for standardized processes, allowing for multiple uses and scale effects
• capture components and its properties in the database and make them available to our development and manufacturing process tools
• perform regular life-cycle analyses on the database

PCB design
In this stage, we will...
• implement analog to high-frequency design, including high-voltage, high-current, rigid-flex, and flex design
• provide high-speed design, including signal integrity simulation
• create a EMC-compliant layout
• optimize the PCB structure and select the best possible supplier

Test system development and functional testing
In this stage, we will...
• create the physical and electrical design for test analysis
• evaluate fault probability and develop our test strategy
• plan and develop test equipment
• create comprehensive test system solutions, from construction and joining technologies to system function
• conduct functional verification and conformance testing as well as load and stress tests
• support test processes throughout the product life cycle

Here’s how you benefit:
From the very start, we collaborate closely with our test engineers and production specialists to create optimal manufacturing conditions for your product, avoiding costly corrective action in later stages and optimizing your cost position (“design-to-cost” principle).

Rapid production of prototypes
In this stage, we will...
• produce an early development / validation sample via fast-track prototyping
• conduct our pre-series and series production on the same manufacturing facilities
• perform a technological first sample analysis, conduct the qualification process for manufacture, and make recommendations for improvement

Production technology for prototypes and series products
In this stage, we will...
• leverage our best-cost-country production strategy using production facilities in Germany and China
• ensure high quality, flexibility, and safety at all locations by using uniform facilities, machinery, and processes
• leverage state-of-the-art manufacturing technologies to produce electronic assemblies and systems
• use ultramodern production equipment for all process stages, from SMT to manual assembly and testing
• optimize production processes for small to medium unit volumes

Here’s how you benefit:
Our lean processes and efficient resource coordination mean your product will be ready for serial production as fast as possible.
**Experts for production and logistics**

**Production and logistics**
This is the process stage where you fully benefit from the breadth of our capabilities: We produce everything from electronic assemblies and subsystems of all complexities to ready-to-use medical devices – all from a single source and tailored to your specific needs.

In this stage, we will …
- offer a wide range of variants for small and medium unit volumes
- pool our materials globally and across a broad customer base to ensure the best possible price/performance ratio
- assign you a dedicated contact person who is just one email or call away
- offer you a logistics solution that is tailored to your needs

**Here’s how you benefit:**
We produce a wide range of variants for small and medium volumes. We know your supply chain and offer you a logistics solution that is tailored to your needs.

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**Experts for After-sales**

When we deliver your turnkey system, our job is far from done. After all, your journey with the new system is just starting, so we remain at your side providing ongoing support to manage life-cycle & availability and help ensure the smooth operation of your investment.

**Life-cycle analyses**
In this stage, we will …
- review the technological and physical availability of assemblies

**Proactive obsolescence management**
In this stage, we will …
- analyze the availability of parts and counsel you on how to ensure availability as we develop and implement the serial production of your solution
- manage technical changes and discontinuations of electrical components. We help you cover your needs for the interim or the remaining life of your solution to avoid expensive supply bottlenecks
- leverage our obsolescence management strategy to protect you from obsolete parts, costly redesigns, uncertain sources, and cost-intensive brokerware

**Dependable spare parts management**
In this stage, we will …
- offer dedicated service logistics processes to make sure spare parts are available fast and reliably
- run rapid diagnosis of returned goods to classify errors and initiate the appropriate measures
- turn your order around as fast as possible thanks to our inventory of replacement parts

**Repair services**
In this stage, we will …
- repair electronic assemblies at our dedicated service center
- guarantee repairs for more than 10 years
- either swap out your product for a replacement from our inventory, or return your specific product to you after repair

**Here’s how you benefit:**
Thanks to dependable and rapid return system, spare parts management and repair flow, your systems and production will run smoothly at all times.

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**Here’s how you benefit:**
We will remain at your side after initial production to help protect your valuable investment for the long term.
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