

SIEMENS



Medical Electronics & Imaging Solutions

Expertise under one roof

Electronic solutions for your medical devices



www.siemens.com/electronicssystem

Innovative technological know-how making great solutions even better

The medical industry – a dynamic setting

The medical industry is highly dynamic – in more ways than one. Constant reform affects health structures worldwide, trendsetting research discoveries are making new treatment methods possible, and the latest technological developments are pushing their way into the market. In addition, top quality, maximum efficiency, and cost sensitivity are now more important than ever.

And at all times, the focus must be on patient well-being. The technical environment is shaped by a comprehensive range of applications and technology fields, short innovation cycles, and highly specialized and complex final devices. These challenging and dynamic conditions are the factors that drive us. Ideas from our customers – your ideas – are what spur us on to peak performance. Our expertise enables us to deliver the highest quality, backed by a certified quality-management system for development and production in accordance with international standards.

A dynamic industry with a broad spectrum of requirements

- Specific and complex technological requirements
- Stringent quality requirements on medical products
- High mix, low to medium volume production

We support you in this environment by offering innovative solutions and short reaction times within a long-term, dependable partnership.

Working with you makes top performance possible

We support you in the medical industry by providing solutions perfectly tailored to your needs. We have expertise under one roof along the entire value chain – from concept to design specifications and implementation to industrialization, production, and support. To meet your requirements, we can either manage the entire product life cycle or concentrate on individual process stages. We offer innovative, sustainable solutions covering the entire spectrum of electronics: Our portfolio ranges from electronic assemblies to subsystems and final devices, all designed to suit your needs as our customer and in accordance with your requirements. At all times, we ensure that your investment is safe far into the future.

Our team spirit and many years of experience are what make us stand out

- Our many years of experience and activities in every area of the medical industry mean that we succeed again and again in producing innovative and cost-optimized solutions in this field.
- We continuously and rigorously standardize and simplify our processes across all of our locations worldwide.
- We pool our materials across multiple customers to ensure the best possible price/performance ratio for all of our customers, at all times.
- Comprehensive life-cycle management guarantees long-term availability of your solutions.
- Our quality management system is certified in accordance with international standards, making us the right partner for your medical technology needs.

By working together closely, we can achieve ambitious goals – yours and ours

One factor that is especially important in our day-to-day business, and one that we actively cultivate, is how we interact. How we network with our customers and suppliers. Collaborating closely with our customers and partners at every stage in the value chain allows us to transform your ideas and your very specific solutions into the highest-quality products. And in the process we create a crucial advantage for you in your own competitive environment.

“Expertise under one roof” – a winning team for you and your medical technology



Business management

Concept

Development

Industrialization

Production
& logistics

After-sales

We implement your ideas in the medical industry – while keeping our eye on the entire value chain

Our key factors for success are the outstanding quality of our products and services as well as our highly qualified and motivated employees. We foster a quality culture that does not rely on past successes but is continuously realigned with the needs of today through a process of ongoing improvement. And naturally, we satisfy all regulations and standards required by law with regard to the medical industry.

Our fields of application

Control solutions

System communication

Human-machine interface

Power solutions

Biosignal measurement

Image processing

Complex electronic solutions of the highest quality for dynamic demands in a medical setting – from concept to final product



Certification

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 Directive, Annex II
- ISO 14001 Environmental Management Systems
- ISO 27001 Information Security Management Systems

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

Concept & development

We support you in developing and realizing your ideas in the medical industry throughout the entire development process, from concept development to design implementation.

Whether we're building on your existing design specifications or you approach us with a product idea, we are optimally prepared to handle your requirements.

Our development process takes all medical regulations into account and represents the state of the art at all times. With all of our solutions, we always keep functional safety requirements in focus. Our professional project management ensures that the details and objectives of your projects in terms of time and costs are carefully managed.

System design and architecture

We take your development idea as the basis from which we create a concept that precisely meets your needs.

- Consulting and comprehensive requirements analysis
- Creation of a complete system design and definition of the system architecture
- Derivation of functional specifications
- Design specification for hardware, software, and mechanical components

Hardware design

- From analog, digital, and mixed-signal design to high-performance, high-frequency applications
- In-depth technical knowledge of standard communication interfaces (for example, CAN, GBit-LAN, Bluetooth, PCIe, PROFINET)
- Characterization using measurement instrumentation and analytic simulations

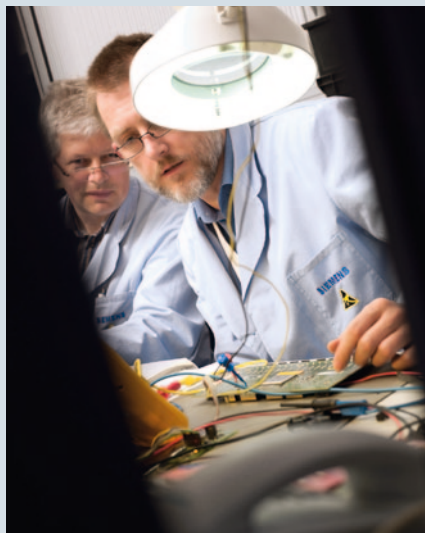
FPGA design

- Comprehensive expertise for complex FPGA design technology and methodology
- High-speed applications, system-on-chip solutions, and standard logic
- Use of pretested IP cores
- Functional verification of the FPGA design
- Consideration of regulatory requirements in terms of FPGA design and configuration management

Software design – embedded software

- Development of embedded software for assemblies to control a wide range of system functions, communications software, or other applications, including those related to safety
- Adaptation and integration of board support packages and development of device drivers based on Linux and QNX
- Integration of communication protocol stacks like CANOpen, PROFINET/PROFISAFE
- Integration of an embedded middleware platform as a powerful basis for the development of control applications

Concept & development



Industrialization – from prototype to series production

The industrialization process involves optimizing the results of development in terms of manufacturability and applying them to series production. Here efficient resource coordination is essential in order to achieve a rapid product introduction.

Close collaboration between our experts in development, industrialization, and production means we can ensure reliable assemblies manufactured at optimal costs and that all quality assurance processes are applied. Involving test engineers and production specialists at an early stage – right from the layout phase – creates the ideal conditions to manufacture your products. We can thus avoid costly corrective action in later stages and help optimize your cost position (“design-to-cost” principle).

Component engineering

- Consulting on the best possible selection of components for new designs and redesign projects
- Standardization based on our component database creates the preconditions for multiple uses and scale effects
- Adding a component to the database makes it available, with all its properties, for the tools used in development and manufacturing processes
- We perform regular life-cycle analyses based on the database

PCB design

- Analog to high-frequency design, including high-voltage, high-current, rigid-flex, and flex design
- High-speed design, including signal integrity simulation
- EMC-compliant layout
- Optimization of PCB structure and selection of the best possible supplier

Test system development – functional testing of medical systems and equipment

- Physical and electrical design for test analysis
- Evaluation of fault probability and test strategy development
- Test equipment planning and development
- Comprehensive test system solutions, from construction and combining technologies to system function
- Functional verification and conformity testing and performance of load and stress tests
- Support for test processes throughout the product life cycle

Rapid production of prototypes

- Fast-track prototyping to produce an early development/ validation sample
- Preseries and series production using the same manufacturing facilities
- Technological first sample analysis, qualification process for manufacture, and recommendations for improvement

Production technology for prototypes and series products

- Best-cost-country production strategy using production facilities in Germany and China
- Uniform plant, machinery, and processes permit high quality, flexibility, and safety standards at all locations
- Use of state-of-the-art manufacturing technologies for the production of electronic assemblies and systems
- Ultramodern production equipment for all necessary stages of the process, from SMT to manual assembly and testing
- Production processes optimized for small to medium unit quantities

Industrialization



Production & logistics

There are many facets to our offerings: To meet your needs, we produce everything from electronic assemblies and complex subsystems to final medical devices – all from a single source. Our production and logistics are structured to cope with complex demands. We are known for the wide range of variants that we produce in small to medium volumes. We pool our materials globally and across a broad customer base to ensure the best possible price/performance ratio in meeting these requirements. For you, our customer, this means maximum cost efficiency.

We also ensure that every customer has a dedicated contact person who will be in constant touch with them. We understand your supply chain and can offer you a logistics solution that is tailored to your needs.

After-sales

Life-cycle analyses

- Reviewing the technological and physical availability of assemblies

Proactive obsolescence management

- Analysis of availability of parts in the development and series production process and consulting on alternative solutions that will ensure availability
- Management in a context of technical changes and discontinuations of electrical components, including coverage of interim or remaining needs, to avoid cost-intensive supply bottlenecks
- Our obsolescence management strategy offers the optimal protection against obsolete parts, costly redesigns, uncertainty of sources, and cost-intensive brokerware

Dependable spare parts management

- Dedicated service logistics processes for rapid and dependable availability of spare parts
- Rapid diagnosis of returned goods to classify errors and initiate the appropriate measures
- An inventory of replacement parts ensures rapid turnaround times

Repair services

- Dedicated service center to repair electronic assemblies
- Guaranteed repairs for more than 10 years
- If an exchange is required, products can be drawn from a pool or customer-specific products can be delivered back to the customer as part of a repair-and-return process

Production & logistics



After-sales



On account of certain regional limitations of sales rights and service availability, we cannot guarantee that all solutions and services included in this brochure are available through the Siemens sales organization worldwide.

The information in this document contains general technical descriptions of specifications and options as well as standard and optional features which do not always have to be present in individual cases.

These components and configurations are neither finished medical devices nor finished devices for the industrial sector. Compliance with all laws and regulations that are applicable to finished medical devices or industrial devices are the responsibility of the assembler/manufacturer of the finished device.

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Global Business Unit

Siemens AG
Henkestr. 127
91052 Erlangen
Germany
Phone: +49 9131 84-0

Local Contact Information

Siemens AG
Healthcare Sector
Medical Electronics & Imaging Solutions
H CP CV ME
Allee am Roethelheimpark 2
91052 Erlangen, Germany
Phone: +49 9131 84-4300
Fax: +49 9131 84-6748
cv-me-solutions.healthcare@siemens.com

Global Siemens Headquarters

Siemens AG
Wittelsbacherplatz 2
80333 Muenchen
Germany

Global Siemens Healthcare Headquarters

Siemens AG
Healthcare Sector
Henkestr. 127
91052 Erlangen
Germany
Phone: +49 9131 84-0
www.siemens.com/healthcare

Legal Manufacturer

Siemens AG
Wittelsbacherplatz 2
DE-80333 Muenchen
Germany