The specialists

for Healthcare, Pharma and Medical Technology

senetics®
healthcare group GmbH & Co. KG

| Consulting | BioLabs | Test Lab | Product Development | Production | Marketing | Academy |

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Introduction

Dr. Wolfgang Sening

General Manager

„Since 2009, senetics has been your guarantor for competent support in the field of medical devices, medical technology and the neighboring sectors of pharmaceuticals, laboratory equipment and cosmetics. Since the start of my company, various competence centers have emerged, which we make available to you as a “One-Stop-Shop“ for interdisciplinary services in the healthcare market. The competent team of senetics includes engineers, medical technicians, physicists, biologists, chemists and various experts in the field of medical devices. The “red thread“ of our services for you starts with the innovative idea for a product, its feasibility, development and implementation, prototyping, testing, the “paperwork“ for the approval up to the “placing on the market“ and also the market entry support. Of course, not all customers make use of all services, because sometimes it’s “simply“ necessary to carry out a product test or to prepare a clinical evaluation. Our customers are always our focus. Customer satisfaction and competent professional support are always our top priorities. Be assured that we make your product a success with all our capabilities!“

Company portrait

About us

senetics is an innovative and interdisciplinary service company based in the Franconian margraviate city of Ansbach. The focus is on the areas of medical devices, medical technology, laboratory equipment and pharma!

senetics is your one-stop-shop for contract development, testing, inspection and approval of medical devices. All tasks - from the development of innovative devices, applications and assemblies, as well as their prototyping up to series production - can be successfully implemented. The portfolio is rounded off by competencies in the areas of regulatory affairs, approval according to MDR/FDA, standard-compliant technical documentation, the establishing of a quality management system and laboratory tests and inspections.

senetics accompanies you from the first innovative idea to market success!

Our quality management

senetics is certified according to the internationally valid quality management standard ISO 13485 and includes a GLP (Good Laboratory Practice) testing laboratory for medical devices. In addition, senetics works according to the international GMP (Good Manufacturing Practice) specifications and ISO 17025. senetics is a authorized consulting company at go-inno (Federal Ministry for Economy and Climate Protection). Likewise, senetics is a member of the Bavarian Environmental and Climate Pact and the Bavarian Family Pact and implements measures for this.

Customer feedback

"I would like to take this opportunity to thank you very much. A real enrichment and helpful support."

"Thank you for everything. I will come back to you when the time comes. I'm looking forward to a TOP cooperation again."

"To get through the initial certification without any deviation is a great result for us. Thank you very much!"

„I looked through the drafts - respect - great job. Looking forward to see the final documents!“

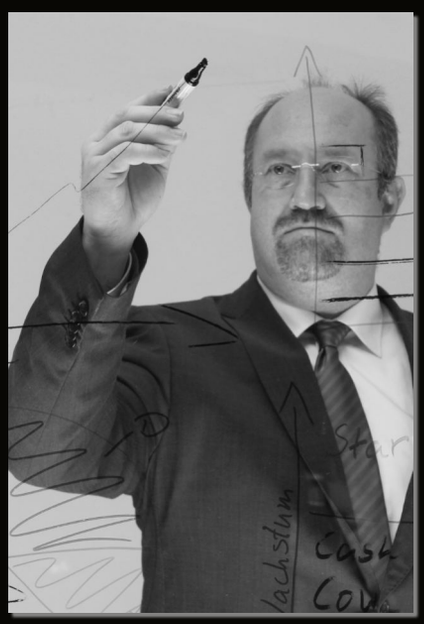
„Thanks to the whole team for the great implementation in our company. It was very gratifying for us that you advised us so competently.“

★★★★★

Your feedback is important to us!

We are constantly working to improve and offer an attractive portfolio.

History



2009

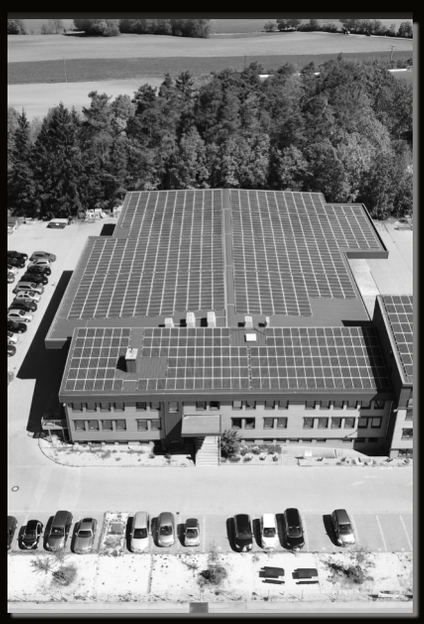
- Foundation of senetics healthcare Dr. Wolfgang Sening
- Move into first office in the Medical Valley Center in Erlangen
- Hiring of the first employees
- Accreditation as advisor in “Gründer-coaching Deutschland“ (aided by KfW)
- First orders in the area of consulting and development
- Establishment of various medical technology training courses

2010-2012

- Expansion of the business premises and enlargement of the area
- First awards of the senetics Innovation-Award
- Foundation of the NeZuMed network
- Organization of the first cooperation congress on medical technology
- Various accreditations as consultant and juror
- First awards
- Participation in various trade fairs abroad

2013-2015

- Foundation of senetics healthcare group GmbH & Co. KG
- Expansion of the business premises and enlargement of the area
- Construction of a bio- and electronics laboratory
- Foundation of the database healthcare-network.eu
- Foundation of the network CarboMedTech
- Publication of „Kompetenzatlas Medizintechnik“
- Introduction of ISO 13485 and ISO 9001



2016-2018

- New, innovative location in Ansbach
- Expanded development, productioin and laboratory capacities
- ISO 13485 and ISO 9001 certification
- BioLabs - Certification according to ISO 17025
- Member of the Environmental Pact of Bavaria
- Expansion of the departments
- Awarded as a training company of the IHK
- Participation in international projects

2019-2021

- 10th anniversary with big celebration
- BioLabs - Certification according to GLP
- Purchase of a new company location in Ansbach
- Expansion of the business premises and enlargement of the area
- Member of the Family Pact of Bavaria
- Award Catrene - as best EU-F&E-Project
- BioLabs – Interlaboratory tests passed with great success
- Commitment to IHK examinations

2022

- Expansion of the business premises and enlargement of the area
- Successful launch of various customer products
- Further award as training company and commitment to IHK examinations
- Expansion of the service portfolio
- Further modernization of the company building
- Recertification according to ISO 13485
- Extension of the inspection and testing possibilities

Our services

Consulting

Approval of medical devices, FDA, MDR, IVDR. Establishment of QM systems e.g. ISO 13485, competition/SWOT analyses, consulting on medical devices and market entry. HACCP/Food. We advise you competently!

Sections:

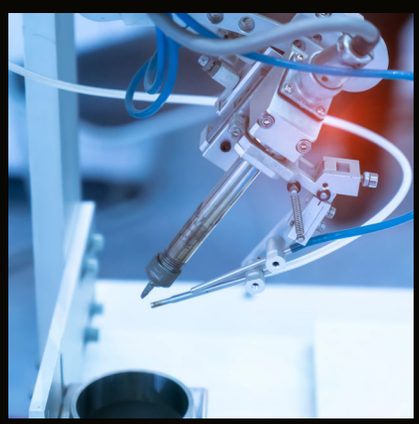
- Regulatory Affairs
- Technical Documentation
- Quality Management & Risk Management
- Strategy & Business Expansion

BioLabs

Biological and chemical tests, as well as individual tests according to customer requirements. We carry out your test with the highest care and in compliance with current standards!

Sections:

- Sterility
- Biocompatibility
- Clean room monitoring
- Cleaning & Sterilization Validation
- Antimicrobial Efficacy
- Customized testing

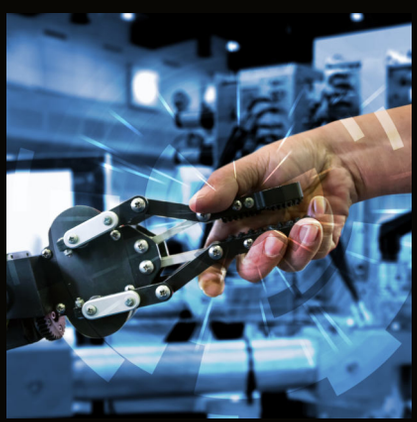


Test Laboratory

Standard-compliant, mechatronic tests for medical devices, as well as individual tests according to customer requirements. We support you in the safety of your product!

Sections:

- Product safety check
- Improvement product shelf life
- Optimization product features
- Risk minimization
- Documentation review

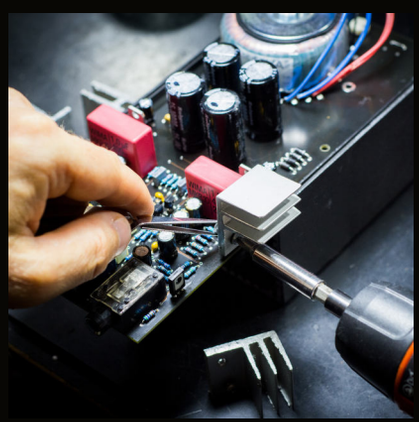


Product Development

Development of innovative components, accessories, assemblies or the complete product. Together with you we develop a solution. We turn your idea into a marketable product!

Sections:

- Medical devices
- Electromedicine
- Therapy devices
- Drug applications
- Prosthetics & Implants
- Wearables & smart sensor technology



Production

Development transfer and series transfer, e.g. Directly after completion of development, with all activities required by the standard. We are your strong partner for your production project!

Sections:

- Series production
- Supply-Chain-Management
- Suppliers- and inspection equipment Management
- Process control
- Traceability
- Quality assurance

Academy

Through our seminars we accompany you from the market analysis, the development, the production, the „bringing into circulation“ to the marketing. We help you to qualify your employees!

Categories:

- Biological requirements
- Development & Documentation
- Management, Marketing & Sales
- Qualifying further education
- Legal requirements, regulations & standards

Regulatory Affairs & QM Consulting

Intelligent solutions for the approval of your medical devices (MDR) and IVD (IVDR)

The legal requirements for medical devices and in vitro diagnostics (IVDs) are very strict and complex. The Medical Device Regulation (MDR) and the In-vitro-Diagnostic Regulation (IVDR) lay down comprehensive requirements. As a total service provider, we offer expertise in regulatory and normative topics related to medical devices, IVDs, laboratory equipment and pharmaceutical applications. We at senetics are at your side with our expertise - efficient, competent and always up-to-date.

- Do you want to develop a medical device or IVD compliantly and bring it to market?
- Would you like support in maintaining technical documentation, clinical evaluation, PMS or even PMCF?
- Or would you like to establish a quality management system according to ISO 13485 or ISO 9001 and be certified accordingly?
- Are you new to the medical technology industry and need support entering the market?

Whatever your questions about guidelines, regulations, QM systems or approval procedures - we are there to support you.

Consulting
Regulatory Affairs and QM

Contact us!

+49 981 9724 795-0 or info@senetics.de

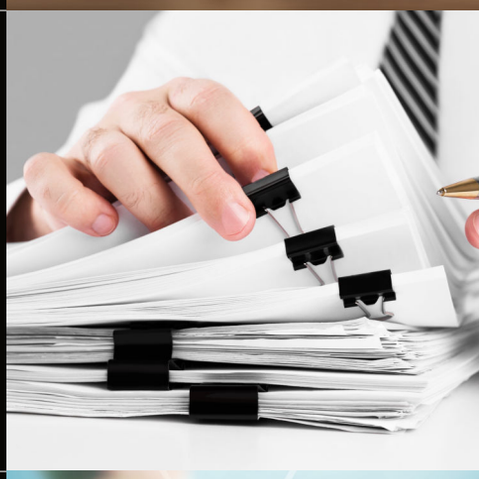
With us you will reach your goal !

Regulatory Affairs

- Consulting according to the „old“ guidelines
  - MDD (93/42/ EWG) | IVDD (98/79/EG) | AIMDD (90/385/EWG)
- Approval EU according to the „new“ regulations
  - MDR (2017/745) | IVDR (2017/746)
- Approval in the USA after
  - FDA 510(k) Premarket Notification | FDA Premarket Approval (PMA)
- Implementation of the new MDR and IVDR in ongoing operations
- Health economic consideration

Technical documentation according to current requirements

- Creation and maintenance of technical documentation according to MDR/ IVDR
- Revision of your technical documentation after deviations
- Clinical evaluation according to MEDDEV 2.7/1 REV. 4 (MDD/MDR)
- Clinical trials according to ISO 14155
- Position of the „Safety Officer“ according to § 30 MPG
- Position of the „Responsible Person for Regulatory Requirements“ according to EU Regulation 2017/745 (MDR, Art. 15)



Quality management and risk management

- Introduction of ISO 13485 and ISO 9001
- Introduction of a QM system according to FDA 21 CFR 820 / GMP
- Gap-Analyses
  - ISO 13485 vs. FDA 21 CFR 820 / GMP
  - ISO 13485 vs. ISO 9001
  - IATF 16949 to ISO 13485
- Implementation of the risk management process according to ISO 14971
- Implementation of internal audits and supplier audits
- Standard-compliant documentation according to ISO 13485, GMP, GAMP

Strategy and business expansion

- Consulting for physicians and start-ups in the field of medical devices
- Support for diversification in the healthcare sector for suppliers
- Advice on the acquisition of companies in the healthcare industry
- SWOT analysis for companies under medical technology aspects
- Strategy development and technical due diligence

Test laboratory - Technical tests

Standard-compliant, mechatronic tests for medical devices, as well as individual tests according to customer requirements

Standard-compliant testing prior to approval of a medical device is an important component in product development and approval. In order not to endanger patients, users or third parties, various tests to ensure the basic safety and performance requirements are required even before approval. In order to successfully pass these tests prior to approval, it is necessary to undergo testing with parts of the product already during development.

- You would like to have the functional safety or usability of your medical device tested?
- Mechanical and/or electronic tests or climatic tests to be performed?
- Do you want to have your medical device validated for a disinfection procedure?
- Or do you need to have the resistance of the surface coating tested?

Using our combined biological and engineering expertise, we can provide you with comprehensive support and ensure the safety of your products at every stage of the development / supply chain. We are also happy to take time for customer-specific requests!

Test laboratory

Electronics and mechanics

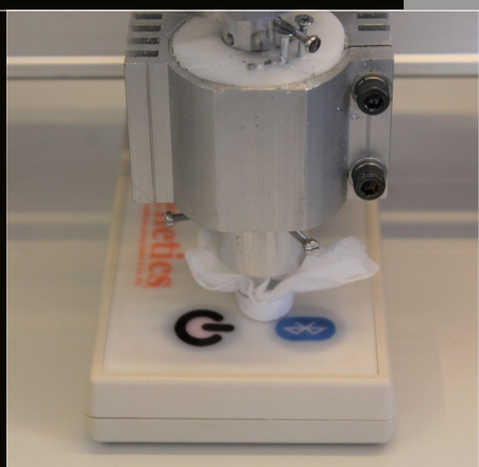
Contact us!

+49 981 9724 795-0 or info@senetics.de

We test your product !

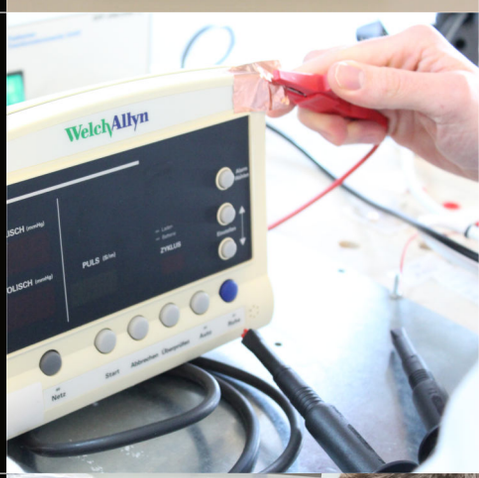
Testing for disinfectant resistance

- Wipe disinfection with disinfectant on normative basis following ISO 105-X12
- Testing by immersion according to ISO 2812-1
- Assessment of coating damage according to ISO 4628-1
- Determination of the disinfectant performance
- Mechanical cleaning and disinfection according to ISO 15883
- Steam sterilization process based on ISO 17665
- Disinfectant testing according to customer-specific test scenarios
- Long-term durability of surgical instrument marking



Normative tests and functional safety testing

- Certain tests of ISO 60601-1 accompanying the development: e.g. testing for first-fault-safety, testing of electrical safety, testing of dielectric strength, testing of the insulation concept.
- Testing of medical devices for the home environment (EN 60601-1-11)
- Testing of the serviceability (EN 60601-1-6)
- Testing the alarm systems (EN 60601-1-8)
- Testing of special supplementary standards of the ISO 60601-1-X series
- Testing compliance with EN 62304



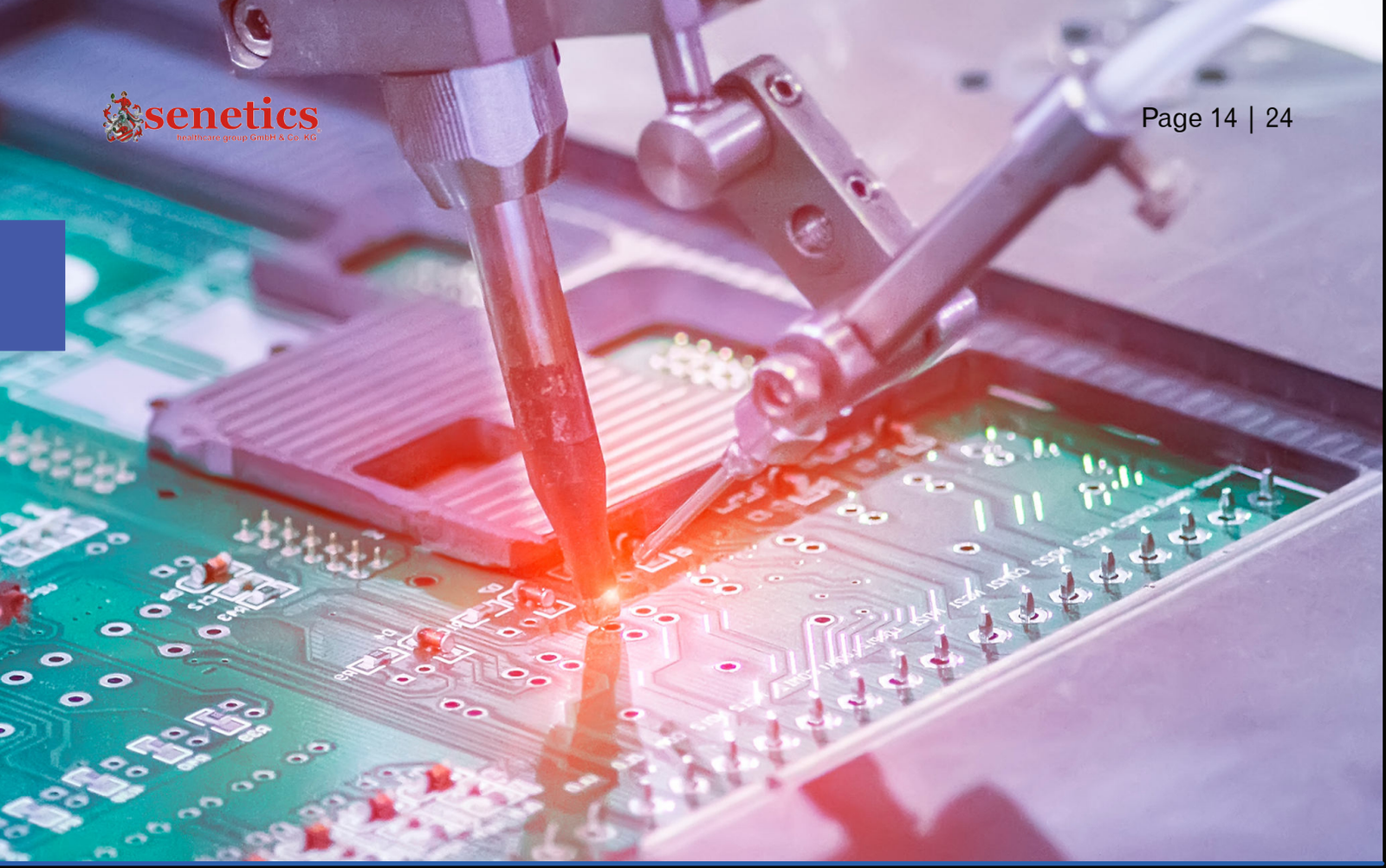
Wear/climate tests | Aging/transport simulation

- Accelerated aging of products by means of climate chamber
- Drop & temperature testing of packaging units according to ISTA 2A
- Shock test by free fall according to ASTM D5276-19
- Conditioning according to ASTM D4332-14
- Assessment of coating damage according to ISO 4628-1

The following standards and requirements can be tested by means of test chamber conformity: ISO 60068-2, ISO 60601-1, ISO 6270-2, ISO 4892-2, ASTM F1980-16, ASTM D4332, ICH Q1A-Q1E, WHO Technical Report Series 953, Annex 2

Product/Customer-specific tests (examples)

- Validation of medical devices on biological and artifical skin models
- Respiration simulation for the validation of the germ load
- Cleaning validation for ventilators and pulmonary function diagnostics
- Verification of product safety and improvement of product shelf life
- Documentation review and risk mitigation measures
- Tests to determine the UDI resistance
- Optimization of product properties
  e.g. abrasion resistance, UV stability, tensile strength or compressive stress



Product Development according to ISO 13485

Innovation and competence - implemented according to ISO 13485 in your product

The development of innovative products, technologies or assemblies is the core of the medical technology industry. At senetics, innovative ideas become finished products that convince. Our competencies cover all healthcare areas such as medical devices, in-vitro diagnostics, laboratory equipment, as well as related software and firmware developments. Furthermore, our competences are also applied in the automotive sector, e.g. For the analysis of vital parameters for the purpose of driver monitoring.

- Do you have an idea for an innovative medical product and are looking for a partner to support you in its implementation?
- Or would you like to expand your product portfolio and are looking for sparkling ideas for new technologies?
- Do you already sell equipment and would like to have your concept checked or expanded?
- Are you looking for expertise on how to design technical documentation?

Our team of experts will be happy to take over the development of individual components, assemblies or the complete product for you and turn your idea into a marketable product.

Whatever you have in mind - let us know!

Product Development
Innovation and development

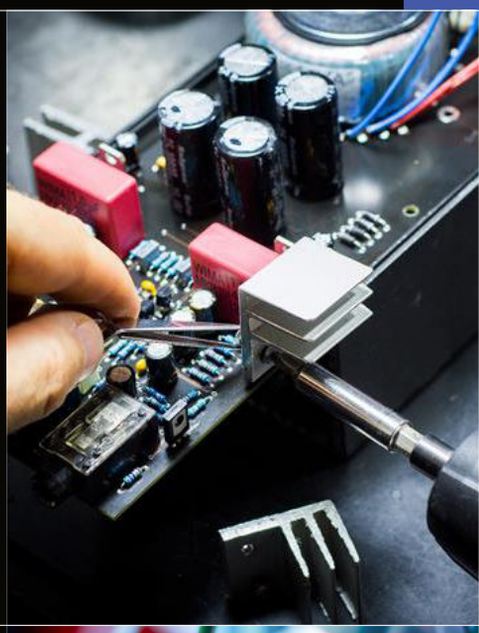
Contact us!

+49 981 9724 795-0 or info@senetics.de

Together we will find a way !

Application areas

- Electromedicine, e.g. controls for wheelchairs
- Diagnostics, e.g. blood glucose monitoring
- Therapy devices, e.g. Vagus-Nerve-Stimulation
- Medication application, e.g. insulin pens
- Prosthetics & Implants, e.g. Implantable Sensors
- Wearables & smart sensor technology, e.g. hydration sensor technology

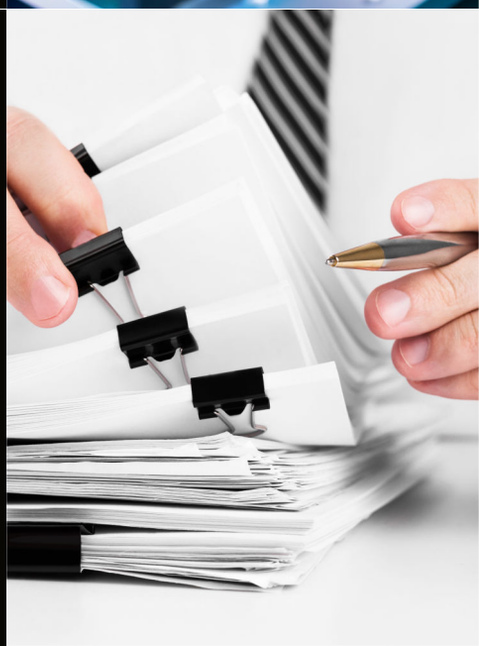


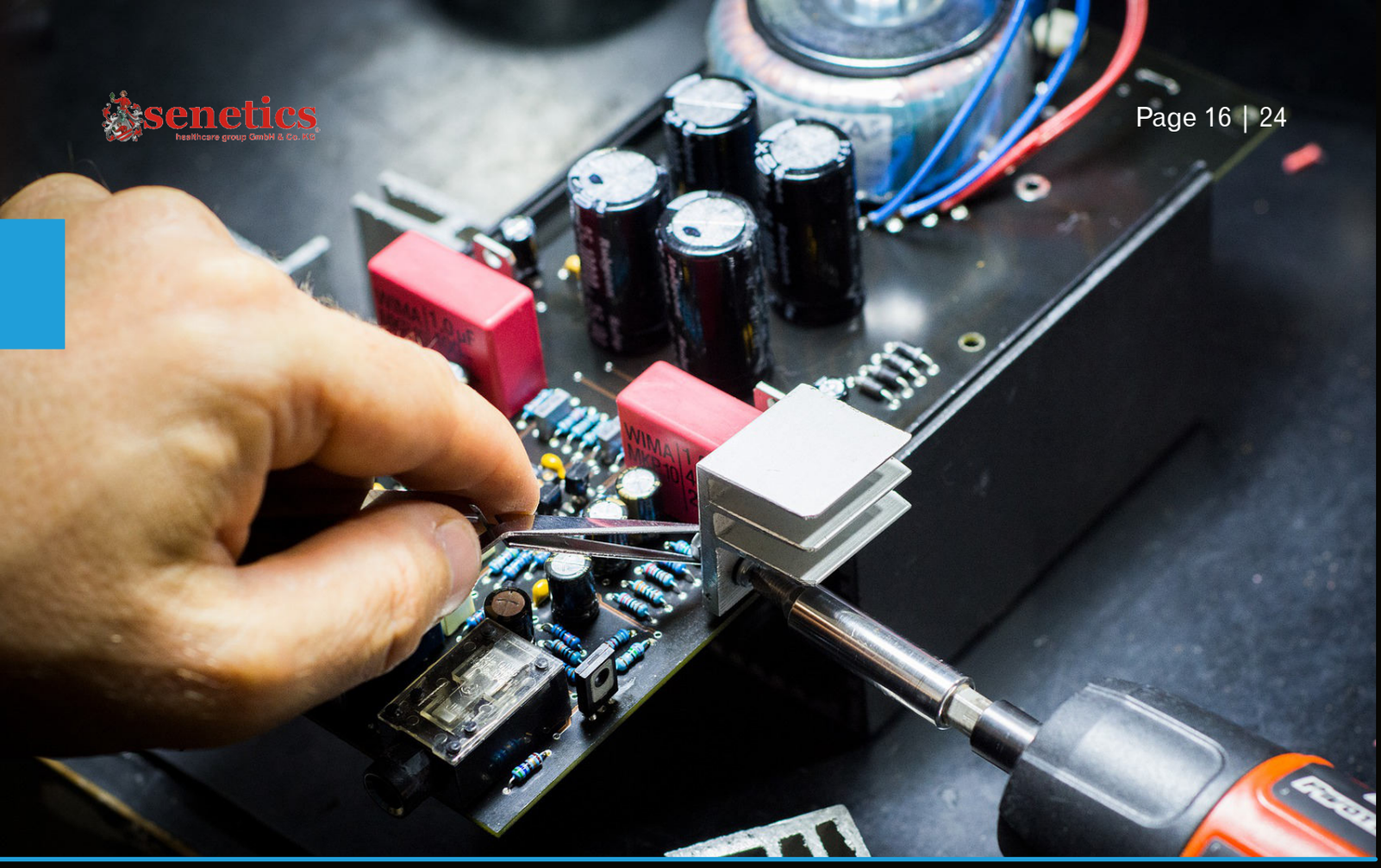
Portfolio of development

- Software development according to IEC 62304, e.g. Standalone or Embedded Software
- Feasibility studies and contract development
- Construction (CAD/CAM), e.g. housing development and design
- Electronics development, e.g. control electronics and power supply
- Simulation and optimization
- Set-up of measuring and test equipment
- Pre-development and demonstrator construction
- Verification, qualification and validation during development

Technical documentation and innovation management

- Accompanying technical documentation in accordance with FDA, MDR and IVDR
- Preparation of the risk management file according to ISO 14971
- State of the art - Analysis and Patenting
- Software documentation according to IEC 62304
- Development according to the requirements EN 60601





Production

High quality production of your ideas according to ISO 13485 - Made in Germany

Our competent team offers you reliable and perfected production from small batches (as of quantity 1, if required) through structured planning and technical know-how. We master the high requirements of ISO 13485, the fulfillment of which is necessary for medical devices, for you - both through strict quality controls and through an excellent supplier pool and supplier management.

- You would like to have your product manufactured to a high quality at market launch, e.g. in small batches?
- Your products are already successful and you are looking for a competent contract manufacturer?
- Or would you like to have your products packaged and sterilized in a compliant manner?
- Is there an idea that you want to realize in a prototype?

We take care of the development transfer and series production transfer of your product directly after completion of the development with all activities required by the standard. You will receive a finished and high-quality product from us, which meets the high requirements of the American Food and Drug Administration (FDA) as well as the legal requirements - Medical Device Regulation (MDR) or In-vitro-Diagnostic Regulation (IVDR).

We are your strong partner for your production project of all batch sizes!

Production
Small and medium series

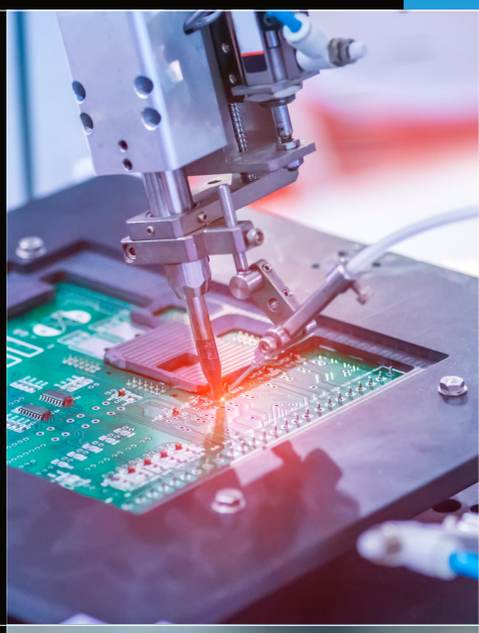
Contact us!

+49 981 9724 795-0 or info@senetics.de

We design manufacturing in perfection !

Series launch

- Small series for clinical trial
- Series introduction and design transfer
- Supplier selection and qualification
- Ensuring the traceability of all components
- Production planning
- Process validation (DQ, IQ, OQ, PQ, MQ)

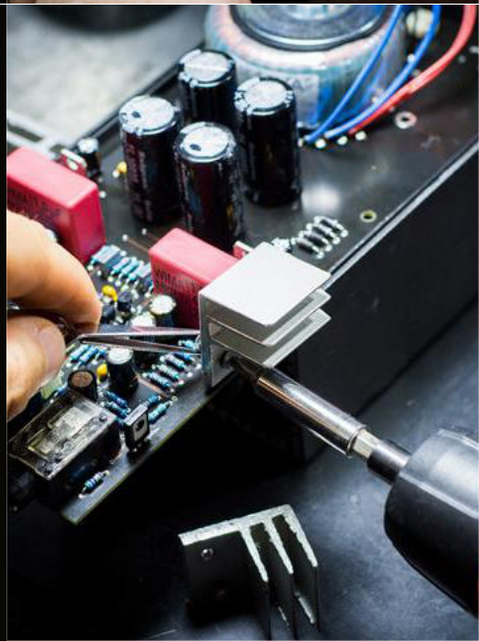


Manufacturing of the components and the product according to ISO 13485

- Production of individual components, small, medium and large series
- Supply-Chain-Management & Logistics
- Quality assurance (100% control possible)
- Order- Cleaning/Packaging/Sterilization
- Assembly and testing services
- Clean production up to ISO class 1 - assemblies

Custom made and manufacture

- Machining of plastics and metals by means of CNC
- Different 3D-printing-methods of plastic parts
- Deep drawing and painting
- Assembly and testing of printed circuit boards
- Assembly of cables and cable harnesses
- Manual assembly of subassemblies in the clean lab
- Assembly, e.g. in microbiological workbenches (clean room)



Academy

Training and continuing education for medical devices at the highest level

The medical device and pharmaceutical industry is becoming increasingly complex. In order to be able to react competently and reliably to these changes, continuous training is important. The qualified instructors from senetics support you in staying up to date and achieving optimal results. Our training program optimally prepares you and your employees for the requirements in the medical technology industry, upcoming regulatory changes or the expansion of your service portfolio.

- You would like to train yourself or your employees to be able to prove higher qualifications?
- Would you like to be regularly updated and informed about all important changes in the medical technology industry?
- Or would you like to deepen or refresh your knowledge?

Our competent team of speakers offers you interesting, instructive and appealing lectures in the areas of management and sales, legal requirements and regulations or further training of employees. Always stay up to date with the senetics academy!

Academy
Seminars and in-house training

Contact us!

+49 981 9724 795-0 or info@senetics.de

Smartly trained with our courses !

Seminars and Inhouse-Trainings

Qualifications and degrees obtained at senetics Academy are highly regarded in the medical device, pharmaceutical and supplier industries. The success of our seminars lies in the focus on the "healthcare industry" combined with many years of expertise.

„Very informative and well structured seminar"
BBraun Melsungen AG

„Perfect learning environment, I really enjoyed the basic course and I am already looking forward to the advanced course!"
Siemens Healthcare GmbH

„Very comprehensive, interesting all-round overview. Very good application examples and despite the complexity well understandable!"
Weber GmbH & Co. KG

„Very good presentation of complex content. Many interesting and helpful tips!"
Boehringer Ingelheim Pharma GmbH & Co. KG

Our comprehensive seminar offer

- Suppliers in medical technology - market entry, regulations, requirements
- Legal requirements for medical devices in the EU
  - The new Medical Device Regulation (MDR), the new In-vitro-Diagnostics Regulation(IVDR) and the Medical Devices Act (MPG)
- Legal requirements for medical devices in the USA
  - The Food and Drug Administration's (FDA) quality management requirements under 21 CFR 820 QSR.
- Quality management for medical devices according to ISO 13485
- Risk management for medical devices according to ISO 14971
- Audits and inspections - preparation, conduct and handling of findings
- Clinical evaluation for medical devices - literature trail vs. clinical trail
- Biological evaluation of medical devices
- Clean production in the clean room - ISO 14644 and VDI 2083
- Software for medical devices - IEC 62304
- Structure of the technical documentation according to current MDR requirements
- Development of medical devices and testing according to EN 60601

BioLabs - Biological testing

Biological and chemical tests, reliable and compliant with ISO 17025 and Good Laboratory Practice(GLP), as well as individual tests according to customer requirements

In the medical device industry, high product safety is essential. According to regulatory requirements - Medical Device Regulation (MDR) or In-vitro Diagnostic Regulation (IVDR) - different biological and chemical tests have to be performed for the approval and routine testing of medical devices. Our BioLabs performs all relevant biological and chemical tests for you and supports you to meet the biological safety according to the relevant standards, e.g. ISO 10993, ISO 11737 etc.!

- Need to test your medical device for biocompatibility?
- Your products should be tested for contamination by particles, microorganisms or endotoxins?
- You want to prove the effectiveness of your disinfectant?
- Or do you want to test your cleanroom for germ load limits?

senetics BioLabs offers you comprehensive expertise in the performance of biological and chemical tests and guarantees work with the highest qualifications.

BioLabs
Biological test laboratory

Contact us!

+49 981 9724 795-0 or biolabs@senetics.de

We make your product safe !

Determination of the germ load

- Determination of Bioburden and product sterility according to ISO 11737-1 and -2
- Examination of the total microbial count on products and their microbial characterization (microbial identification by MALDI-TOF analysis, Multicolored series)

Verification of biocompatibility according to ISO 10993-1, USP and Ph. Eur.

- Testing for skin irritation on the in-vitro skin model and intracutaneous reactivity according to ISO 10993-23
- Cytotoxicity test according to ISO 10993-5
- Endotoxin tets according to Ph. Eur. 2.6.14 (LAL-Test)
- Preliminary tests for mutagenicity studies according to ISO 10993-3
- Ames-Test according to ISO 10993-3
- In vitro chromosome aberration test for mammals according to ISO 10993-3
- Mouse Lymphoma Assay according to ISO 10993-3
- Micronucleus Assay in vitro in human lymphocytes according to ISO 10993-3
- Hemocompatibility according to ISO 10993-4
- Implantation test according to ISO 10993-6 and USP 88
- Residual gas test according to ISO 10993-7
- Skin sensitization, local lymph node test (LLNA) according to ISO 10993-10
- Test for Irritation, Intracutaneous Reactivity according to USP 88
- Subacute systemic toxicity according to ISO 10993-11
- Acute systemic toxicity according to ISO 10993-11 and USP 88
- Subchronic toxicity according to ISO 10993-11
- Chronix toxicity according to ISO 10993-11
- GC-MS/FID analysis according to ISO 10993-18
- ICP-MS analysis according to ISO 10993-18
- HPLC-MS analysis according to ISO 10993-18
- Particulate impurities: Test according to USP 788; Ph. Eur. 2.9.19

Clean room monitoring according to ISO 14644, EN 17141, VDI 2083 and GMP

- Monitoring and determination of particle and total microbial counts on surfaces and in the air
- Hygiene and behavioral training, hazard prevention

We make your product safe !

Validation of cleaning, sterilization and Disinfection

- Verification of the information in the IFU according to ISO 17664
- Control, verification and validation of cleaning, disinfection and sterilization among others according to ISO 15883 and ISO 17665
- Effectiveness of disinfectants

Antimicrobial efficacy of surfaces and textiles

- Antimicrobial efficacy according to JIS Z 2801 / ISO 22196
- Testing of textiles according to ISO 20743

Verification of packaging and labeling

- Verification of the machine-readable quality of the UDI marking
- Testing for seal tightness of packages

Requirements for medical face masks - EN 14683

- Determine filter saturation with artificial respiration
- in-vitro determination of bacterial filtration efficiency (BFE)
- Method for determining the breathability (pressure difference)

Purity of orthopedic implants according to ISO 19227

- TOC analysis
- THC analysis

NeZuMed

Netzwerk für innovative Zulieferer in der Medizintechnik

Become a network member or network partner and benefit from the advantages!

- Support for market success in medical technology
- Information on news from the medical device industry
- Networking/ cooperation projects between the network partners
- Information on state subsidies
- Free participation - NeZuMed network meetings with lectures
- Exclusive participation - NeZuMed trade fair joint stands
- Free listing and linking - www.nezumed.de
- Free listing - Kompetenzatlas Medizintechnik
- Free Basic Listing - Online-Portal www.healthcare-network.eu

Visit us at www.nezumed.de

In collaboration with

healthcare-network.eu
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