

gerresheimer



Customer-Specific Drug Delivery Systems, Medical and Diagnostic Products

We turn your visions into products, ready for market.



www.gerresheimer.com

Our Services

Full Service – from your idea to global logistics

Technical Competence Centers (TCC) in Europe, the United States and Asia

Product and Process Development

From concept development, through the industrial design, product development, and production equipment design to a product that is ready for mass production.

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Mold Making

High-performance injection molds for the high standards of the pharmaceutical and healthcare industry.

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Pilot Plant

Carries out mold trials, as well as optimization and qualification of molds; our quality laboratory performs a series of comprehensive tests.

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Production facilities in Europe, the United States and Asia

Clean Room Production

From injection molding to the finished product.

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Injection Molding in the Clean Room

Innovative injection molding technologies for more functionality and higher design quality.

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Product Finishing

Customized surface decoration: printing, laser marking, metallization, lacquering, sleeving.

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Automation Engineering

Product-specific, high-performance automation solutions for the semi-automated or fully automated clean room production.

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Small Batch Production

Development samples and clinical samples all the way to low volume commercial production at any time during the production.

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Assembly

Joining and gluing techniques as well as assembly of plastic parts, metal parts, and electronics.

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Pharmaceutical Packaging and Filling

Complete solutions including pharmaceutical product loading for products and clinical samples.

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Sterilization, Packaging, and Global Logistics

Many packaging options.

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Product Range

Premium quality for our customers' products

Drug Delivery Devices

Easy handling and high reliability

Inhaler



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Injectables



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Diagnostic Products

Disposable products for diagnostic purposes

Laboratory disposables



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Point of care tests



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Medical Products

The tailored production solution for every product

Lancing devices



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Infusion sets



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Partners of the Pharmaceutical and Healthcare Industry

More safety for people – better quality of life

Gerresheimer AG

Gerresheimer is a leading global partner to the pharma and healthcare industry. With our speciality glass and plastic products, we contribute to health and well-being. With our plants in 14 countries in Europe, Asia and North and South America, we have generated sales of approximately EUR 1.4 billion. With our 10,000 employees worldwide, we produce approximately 15.5 billion products per year, i.e. approximately 500 products per second.

Business Unit Medical Systems

Our Medical Systems business unit produces customized injection molded plastic assembly units, as well as primary packaging made from glass and plastics worldwide. For the global players of the pharmaceutical and medical technology industry, we produce inhalers, insulin pens, auto-injectors, ready-to-fill glass and polymer syringes, cartridges, vials, laboratory disposables, point-of-care tests, lancing devices and lancets as well as infusion sets, micro-infusion devices, catheters and much more.

- 7 production facilities in Europe, North and South America, Asia
- Over 100,000 sqm (1.1 million sqft) production area
- Over 50,000 sqm (540 thousand sqft) clean room in accordance with ISO 14644-1 ISO ISO classes 7 and 8 or respectively GMP classes C and D
- 2,900 employees



Dry powder inhaler produced for the customer Novartis

Our Services

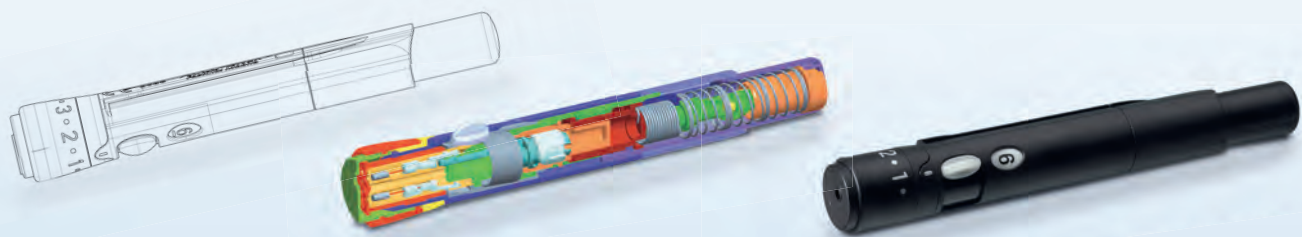
Full service – from development to global logistics

Our service portfolio

Products are born from ideas, mature solutions are the product of visions. As a full service provider, we handle all the phases of the value creation chain. Our process begins from the first idea development to the CE-labeled product ready for sale: concept development, concept studies and ratings with cost analysis, industrial design, product development, process and manufacturing equipment design to mold making, automation engineering, production of clinical samples, large and small batch production in the clean room under FDA/GMP conditions, manual, semi-automated and fully automated assembly as well as fully automatic function tests right through to product finishing, pharmaceutical assembly and filling, sterilization, packaging, and international distribution. Gerresheimer is your one-stop shop.

Flexible start and ending

Starting a project with Gerresheimer Medical Systems provides you with flexible options. We are your product development partner whether you want to implement a first product idea or you want to develop an existing project further. We are your industrialization partner, if you want to optimize a completely developed product specifically for plastics and want to get it ready for mass production. In our Technical Competence Centers (TCC) in Wackersdorf (Germany), Bünde (Germany), Peachtree City (USA) or Dongguan City (China), you are in the best of hands. We are your contract manufacturer for the production of the components in the injection molding process and any further needed processing in our international production facilities in Europe, Asia, as well as North and South America.



Support along the entire process chain: From initial conception right through to the CE-labeled point-of-sale product. This lancing device is a perfect example of our approach to customer projects.

SERVICES AT A GLANCE

- ▮ Product development
- ▮ Industrialization
- ▮ Contract manufacturing



Injection molding in the clean room is in accordance with ISO 14644-1
ISO class 8 in the production facility in Horšovský Týn, Czech Republic.

Technical Competence Center (TCC)

From your product idea to a product ready for sale

Our development centers (Technical Competence Centers) in Wackersdorf (Germany), Bünde (Germany), Peachtree City (USA) and Dongguan City (China) are the “technical heart” of Gerresheimer Medical Systems, both with regard to products and processes. Using the simultaneous engineering method, the TCC maps the entire development process of the products all the way to mass production. Designers, engineers and technicians from various areas work hand in hand here. The results are products that are not only characterized by their high quality and functional reliability, but also by their ability to be mass-produced in a manner designed for plastics. The equipment of the Technical Competence Centers include their own small batch production with clean room in accordance with ISO 14644-1 ISO classes 7 and 8 or respectively GMP classes C and D, a pilot plant, a qualification and validation division for molds and special-purpose machines, a quality laboratory (with its own measuring room with product-specific test equipment), functional testing lab, mold making and mold optimization as well as special-purpose machinery manufacture.

The world at a glance

From the TCC's, Project Management locally schedules all the orders for the different markets and thus ensures that your project is as cost efficient as possible. Experienced project managers control the international resource allocation and coordinate the use of on-site project managers at the international locations.

Knowledge and innovation network

Due to continuous dialogue with universities, technical schools, and renowned research institutions, the TCC is always up-to-date in terms of technology. We collaborate, for example, with the Ostbayerischen Technischen Hochschule (OTH) Amberg-Weiden in the area of materials testing. Some of our other partners include the Institute for Plastics Processing at the RWTH Aachen (IKV), the Fraunhofer Institute for Production Technology in Aachen, the University Regensburg (electrical engineering) and many more.



Wackersdorf
Germany



Bünde
Germany

Your Advantages

of our integrated approach



Peachtree City
USA



Dongguan City
China

Product Development

Understanding the end user
is where development begins

For the past 40 years, we have been developing drug delivery devices as well as diagnostics and medical technology disposal systems on behalf of leading pharmaceutical and medical technology companies. In our development teams in Wackersdorf (Germany), Münster (Germany), Peachtree City (USA), and Dongguan City (China), approximately 50 product and process developers are working on solutions that meet the needs of the market and the users, and that are designed specifically for mass production using plastics. Your advantage: reduced development time, development costs, and project risk, since, whenever Gerresheimer Medical Systems performs the development, plastics optimization is already part of the development. Our development department has its own development laboratory in which first tests are performed at the start of the product development. The equipment was chosen in such a way that the most important system components can be adjusted.





OUR SERVICES

- Development of all types of ideas and product concepts
- Industrial design
- Patent management
- Development of operational concepts as part of the usability engineering
- Analyze design concepts as part of usability studies
- Concept evaluation, feasibility studies
- Development of medical products, drug delivery devices, pharmaceutical primary packaging in accordance with regulations (such as MDR 2017/745, ISO 13485, ISO 15378, FDA 21 (CFR 820))
- Develop process for the manufacturing of the product
- Simulations and tests
- Design optimization
- Design for Manufacturing
- Create functional samples
- Supplier preselection, material selection
- Design of packaging



GATE



**Phase I:
Concept Phase**

In the first project phase, we develop ideas and product concepts for your new device. We understand market requirements, draft the industrial design, take over patent management, develop operational concepts as part of the usability engineering, consider critical sub-functions and develop models. In addition, we analyze design concept as part of usability studies and perform concept evaluations as well as feasibility studies. The result of the concept phase is a **preferred concept** along with a thorough **risk analysis** and **considered market requirements**.



Design concept of a connected add-on device for flow measurement

GATE



**Phase II:
Design and
Development Phase**

In the subsequent project phases, we define product requirements, break down design and develop customers products in accordance with the regulations (for example MDR 2017/745, ISO 13485, ISO 15378, FDA 21 (CFR 820)). We develop the process that is necessary to manufacture the product, analyze the processes for a potential patenting, conduct simulations and tests, and create functional samples. Our service package also includes a preselection of suppliers and selection of materials. The result of the design and development phase is a **completely developed product** with defined production processes and the design freeze.



Modular concept of a smart and wireless connected patch pump

GATE



**Phase III:
Pre-Production
Development**

This phase includes the design verification and the preparation for product validation. Our experts in mold design and automation engineering develop the molds for small batches and special-purpose machines. Mold and automation solutions are not only developed for mass production, but during the prototype and pre-production phase, which saves time. Quality planning develops the measuring equipment in the quality laboratory. If necessary, we manufacture development samples, clinical samples, or stability batches, as well as low volume commercial production in our small batch production with clean room in accordance with ISO 14644-1 ISO classes 7 and 8 or respectively GMP classes C and D. The result of this phase is a **verified product**.



Two-cavity mold for a laboratory disposable

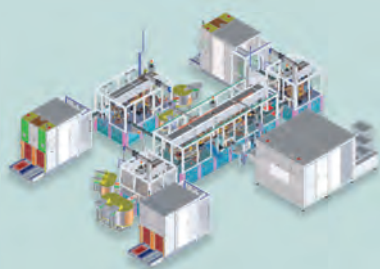


GATE



**Phase IV:
Mass Production
Development**

Phase IV involves the industrialization, the validation of production means, and preparations for the product introduction. Our experts from mold making and automation engineering design, develop and build the high-cavity injection molds and complex robots and systems used for mass production. We qualify the resources, project the global mold and specialty-machinery acquisitions and prepare the product master file. The results of Phase IV are **mass production means and a product validated for mass production.**



Assembly line for an inhaler

GATE

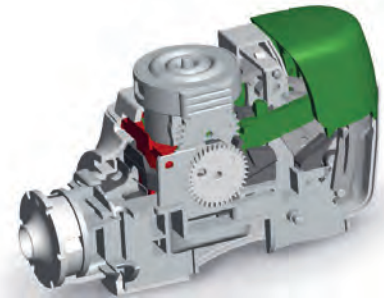


**Phase V:
Mass
Production**

In this project phase, the product is introduced and the lifecycle management started. The result of this phase is ongoing production of the standard parts and/or standard products.



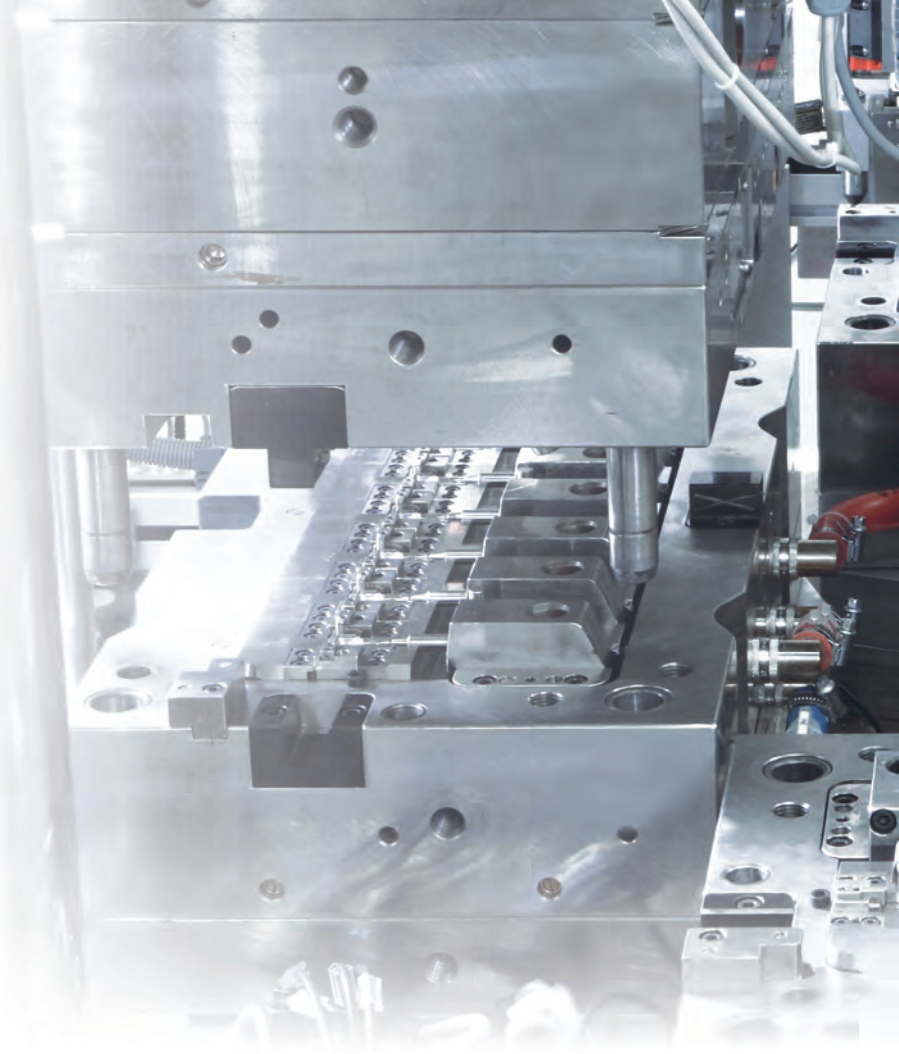
Clean room production in the production facility in Pfreimd, Germany



Multidose Dry Powder Inhaler produced for the customer AstraZeneca

TAILOR-MADE SERVICE PACKAGE

The development of a product undergoes several phases. You decide how many you need our support for: from the start as of the product idea, the entry at an existing stage of development to the further development of an existing product. At the end of the product development, you can decide on what the next steps are. We offer you services that are as individual as your projects.



Mold Making

We construct the tools
for your success

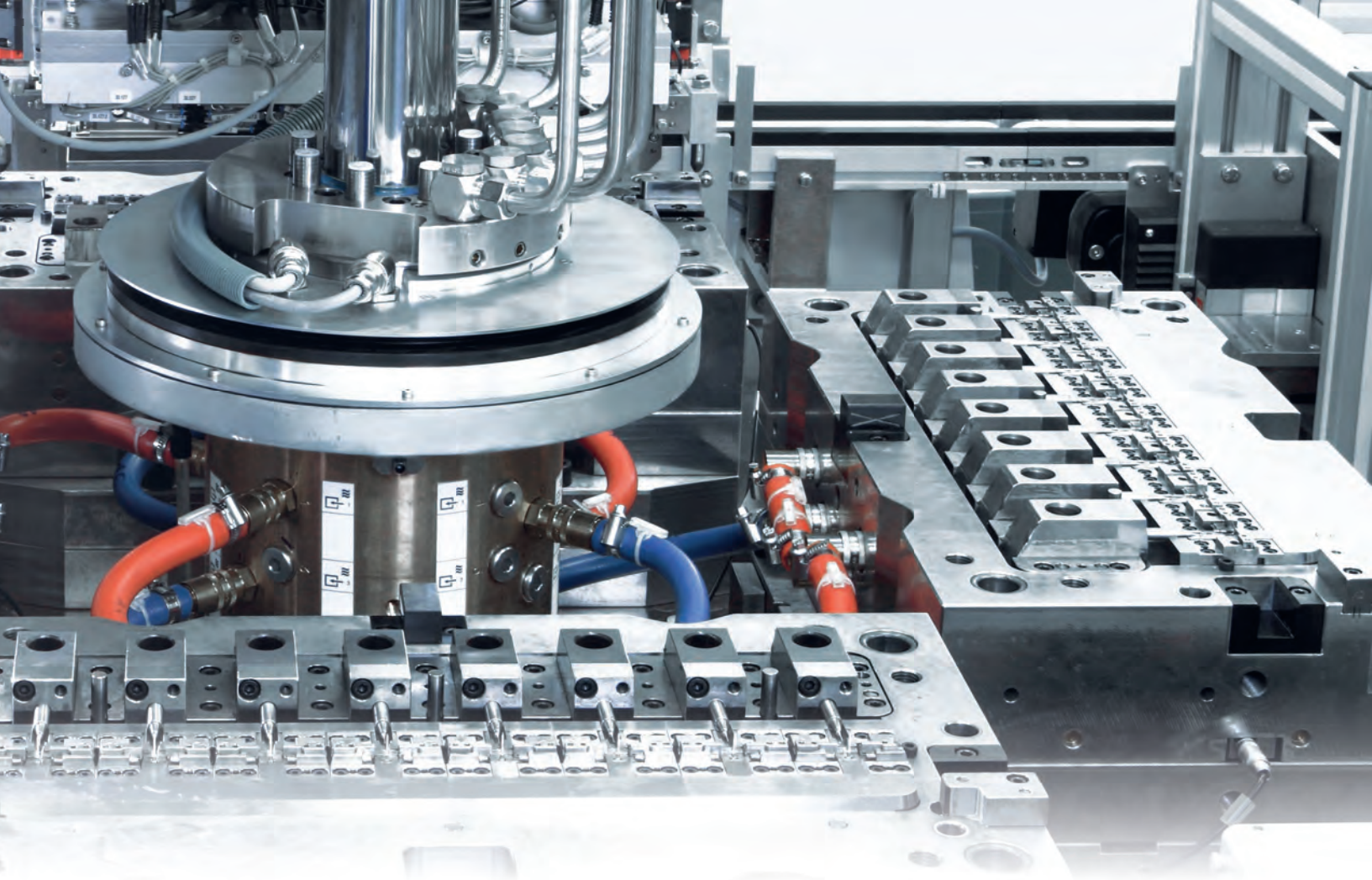
Precision molds for clean room production

Gerresheimer's Medical Systems mold making department has a long tradition. As early as 1958, we started manufacturing sophisticated injection molds, mainly for clean room production. Our precision injection molding tools are designed to meet the high requirements of the pharmaceutical and healthcare industry relating to precision and size accuracy, surface quality, and high output quantities. They are characterized by a 100% repeat accuracy, durability and optimized temperature control for short cycle times.

Our mold making department represents an efficient method of operation. We ensure a fast and smooth production of molds by a segmented structure in mold production and modification and changes division with test molds. Further-more we work with replaceable mold inserts for short maintenance and repair times without additional adaptations. Data consistency from the design to all machines and workbenches as well as the direct link to quality assurance, ensure molds at the highest quality level. We manufacture molds for internal and external production.

Uncompromising quality assurance

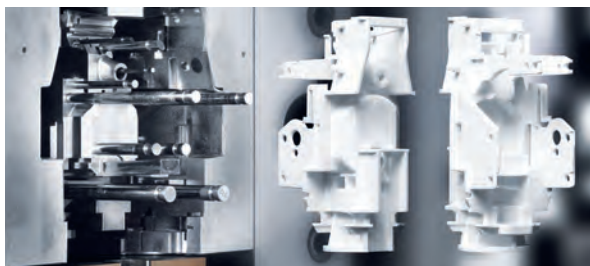
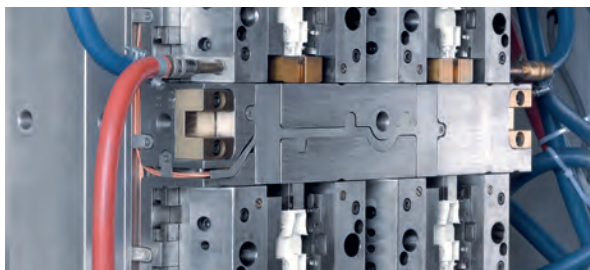
The manufacture of our molds involves the use of the most modern die-sinking and wire eroding systems, precision grinding machines for all processes and micro-HSC milling machines. Uncompromising quality assurance is the highest priority in the entire production process. Precision molds are ultimately the prerequisite for excellent product quality. This is why only the latest measuring equipment, for example, CNC image processing measuring and CNC image processing measuring machines, are used in the internal measurement lab.



Rotary table with four bottom tool halves for insert molding of a cannula with ABS for an infusion set

Most modern mold technologies

More than 65 specially trained employees produce low- and high-cavity injection molds (up to 128 cavities) with a precision in the micro-meter range, single and multi-component molds, indexing plate molds, hot-runner injection molds, molds for insert molding (encapsulation of needles and lancets) and stack molds.



The hot runner mold with eight cavities for an inhaler component is characterized by complex geometries and extraordinarily low tolerances.

Award-winning mold making department

The high quality of our mold making department was confirmed by the top placement in the renowned competition „Excellence in Production“, which is organized by the Laboratory for Machine Tools of the RWTH Aachen and the Fraunhofer Institute for Production Technology.

Gerresheimer Werkzeugbau Wackersdorf GmbH took first place in the category „Internal mold making with up to 100 employees“. In 2014, the Technical Competence Center of Gerresheimer Regensburg GmbH even took first place and thus became “Mold maker of the year 2014”.



Pilot Plant

The TCC pilot plant is our practice-oriented competence center for all injection molding processes. This is where we prove molds to check mold performance and there we measure, optimize and qualify molds. We sample molds and special machinery under near-series conditions and subject them to comprehensive application and processing tests to get them ready for large-scale production. The sampling and mold optimization process in the pilot plant forms the basis of the entire component verification. Important stages during this process are, for example, the setup of stable parameter settings for injection molding. The basis for this is a fractional factorial DOE. In addition, this is where the optical and dimensional component measurements take place in the certified measuring room, which is documented in a comprehensive sample test report. Machine and process-capability documentation and mold trials over defined periods of time (e.g. 4 or 24-hour runs) complete the pilot plant phase.

Quality Laboratory

Quality testing along the entire value creation chain

In the case of drug delivery systems, medical and diagnostic devices, safety is the priority. We therefore carry out extensive testing in the areas of materials, geometry and function during all phases of product origination. Gerresheimer has a measuring lab for the geometric measurement of components, assembly units and finished products, a lab for material analyses and a lab for functional testing with product-specific testing equipment.

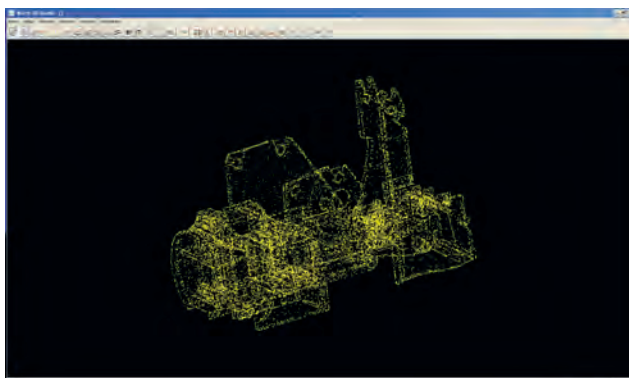


Measuring lab in the Technical Competence Center in Wackersdorf, Germany

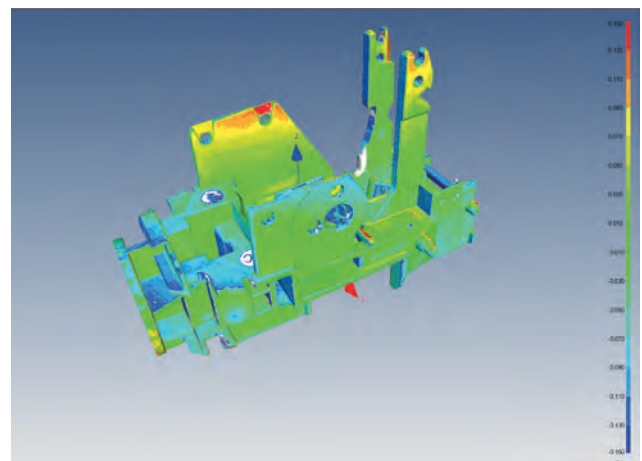
Optical and tactile measurement technology and industrial computer tomography

A measurement laboratory with the most modern measuring equipment ensures that complex mold inserts and filigreed injection molding parts or assembly units can be measured extremely precisely. The complete component measurement is documented in an initial sample test report. The equipment includes various

multi-sensor coordinate measuring machines for optical and tactile component measurements, universal coordinate-reading microscopes, as well as an industrial computer tomograph for the destruction-free measuring and testing of individual component or entire assemblies.



Computer tomograph for the destruction-free measuring and testing of individual components or entire assemblies.





Computer tomograph for destruction-free measuring and testing

Material-specific, physical and chemical analyses

Our material analysis lab is responsible for the incoming goods inspections and raw material approvals worldwide. In addition to the spectroscopic analysis (FTIR) and the established procedure for thermal analysis (MFR/MVR, DSC, TGA), our extensively equipped lab also offers the possibility of a physical-chemical analysis of viscosity, residual moisture and density, as well as an infra-red spectrometer and a thin section microscope. The know-how for the development and execution of customer-specific methods round off our analysis portfolio.

Product-specific functional testing

In our functional testing lab, we develop and qualify test methods to guarantee compliance with product-specific requirements. We ensure more safety for patients with our comprehensive testing of the physical product characteristics, product-specific performance tests, and statistical data analysis during the product development.



Material analysis laboratory



Multi-sensor coordinate measuring machine

Individual qualification packages

The pharmaceutical and medical product industry requires proof of process capability and the reproducible production of an injection mold. Quality assurance is an important point in the national and international laws and guidelines and signifies increased efforts and expenses for the qualification and validation of molds in the development and industrialization phase. In return, however, there is less wear on the mold and a higher parts' quality, resulting in less waste. Mold qualifications are, however, time and cost-intensive. This is why Gerresheimer offers you various mold qualification levels depending on the product, its area of application and regulatory requirement level.

Automation Engineering

Product-specific, high-performance automation solutions for the highly automated clean room production

Together with the development and the construction of the special-purpose machines associated with the molds, we offer our customers high-performance automation solutions. In the pharmaceutical and healthcare industries, automation coordinated precisely with the product, project and processes has a decisive influence on the quality and economic efficiency of production. The technicians, mechanics, electricians, designers, qualification experts, and programmers from the Automation Engineering department are responsible for this task at our Technical Competence Center (TCC).

Most modern means of production for the pharmaceutical and healthcare industry

The 80 member team supports product development with automation competency, develops automation solutions, specifies, designs, builds, procures, and qualifies glass forming, cannula assembly and RTF lines as well as customer and parts-specific assembly lines, testing robots (pressure, flow rate, optical features, force deflection systems), rotary table systems, linear systems, robots to insert and remove parts, packaging systems, pre-production equipment as well as pharmaceutical assembly systems.

All the production systems produced by us meet GAMP (Good Automated Manufacturing Practice) requirements as well as FDA 21 CFR Part 11 and are designed for the production in clean rooms in accordance with ISO 14644-1 class 7/8 or GMP Grade C/D. They are globally standardized at a high quality level. Being an international manufacturer, we also monitor and assist the start-up of our production equipment on the customer's site.



Fully automatic assembly line in clean room according to ISO 14644-1 ISO class 8



Removal handling for injection mold with tray loader (palletizer)

One contact for all project systems

We purchase from experienced suppliers in the market and also build systems ourselves in our in-house special-purpose machinery manufacture. Our in-house qualification department is responsible for qualifying all project systems. For you this means, whether purchased or built by ourselves: you have only one contact for all systems of the project.

Automation – integral element of product development

Automation is an integral component of our product and process development. Our know-how is used throughout the concept and design phase. We do not wait until mass production to develop automation solutions, but develop them in the prototype and pre-production phase to save time. The knowledge gained here can also be passed on to other automatic systems manufacturers when an external solution is planned for series production.



System for separation, loading and testing of needles



The small batch production has a room with a vacuum for filling toxic materials, and, depending on the requirement, it may be done in a protective atmosphere.

Small Batch Production

Development samples, clinical samples up to small batch production at any project stage

Prior to series production, pharmaceutical and medical products run through an exhaustive approval process for which small numbers of units need to be produced repeatedly, for example, as clinical samples, development samples or stability batches. Our Technical Competence Center offers you its own production systems for this task, on which the quick and uncomplicated production of development samples, clinical samples or small series is possible at any point of the project.

The production area of our small batch production for glass and plastics is approximately 1,800 sqm (19,5 thousand sqft). A clean room class 7 and 8 in accordance with DIN EN ISO 14644-1 with about 1,100 sqm (12 thousand sqft) for injection molding and assembly of plastic parts and a clean room GMP class C and D for pharmaceutical glass products with about 370 sqm (4 thousand spft) are available as well. The equipment includes injection molding machines with a clamping force of 65–420 tons, glass forming lines, RTF and cannula assembly lines as well as a line for baked-on siliconization. Project-specific assembly units and specific measuring technologies complete the equipment.



Our small batch production has a class 8 clean room in accordance with DIN EN ISO 14644-1.



The small batch production has its own measurement laboratory with product-specific testing equipment.



The range of services offered by small batch production includes manual or semi-automated assembly, as well as product-specific product finishing such as laser welding and the gluing of tubes with subsequent UV hardening.

Production

From injection molding to the finished product

Seven days a week, day and night: We are producing medical plastic systems with millions of parts nonstop with fully automated production and assembly facilities worldwide – always quick, cost-efficient and with top quality. Prior to the start of production, the setup of the systems is simulated in order to set up the sequence of individual production steps economically and efficiently – short routes for production are the goal.

Worldwide production and clean room capacities

As a global player we think and act international. Therefore, we offer our customers over 100,000 sqm (1,1 million sqft) of production area, of this over 50,000 sqm (540 thousand sqft) of clean room area in accordance with ISO 14644-1 ISO classes 7, 8 and 9 or respectively GMP classes C and D in Germany (Pfreimd and Bünde), the Czech Republic (Horšovský Týn), North Macedonia (Skopje), the USA (Peachtree City, near Atlanta), Brazil (Indaiatuba, near São Paulo) and China (Dongguan City, near Hong Kong). Whether you need a fully automated mass production or semi-automated and manual low volume commercial production of complex and technically sophisticated products: we offer you the best production options worldwide.



Peachtree City
USA



Dongguan City
China



Indaiatuba
Brazil



Skopje
North Macedonia



Coverage of the entire value creation chain in the clean room in accordance with ISO 14644-1 ISO class 8 in the production facility in Pfreimd, Germany.

Our strength: experience

The production of high-quality drug delivery systems, medical, and diagnostic products requires an adequate production environment.

With over 40 years of experience in clean room production according to ISO 14644-1 ISO classes 7, 8 and 9, and coverage of the entire value creation chain in the clean room, we are your specialist for clean room production.

Uniform Manufacturing Execution System (MES)

Top performance in production is no longer possible today without high-performance data processing. We therefore control and monitor production throughout the company with an internationally uniform Manufacturing Execution System (MES).

Automated quality tests that are coupled with the production process and seamlessly documented traceability, ensure that all products meet the required quality standards.



Bünde
Germany



Pfreimd
Germany



Horšovský Týn
Czech Republic



Production

Full services for full customer satisfaction

The full service of Gerresheimer Medical Systems encompasses much more than 100% quality injection molding. It includes many different post-production processing methods – from completion and assembly of modules to optical, haptic and functional finishing through to filling, sealing and packaging of ready-to-use systems.

We even take care of high-quality parts that need to be purchased. Our core competence is in fully automatic large series production and in the manual and semi-automatic small series production of complex and technically sophisticated systems consisting of many individual plastic and purchased parts.



Fully automatic insertion of a spring into an auto-injector in the clean room according to ISO 14644-1 ISO class 8 in Pfreimd, Germany



Injection molding and assembly of inhaler in the ISO 14644-1 ISO class 8 clean room in Dongguan City, China



Injection molding in the clean room according to ISO 14644-1 ISO class 8 in Pfreimd, Germany.

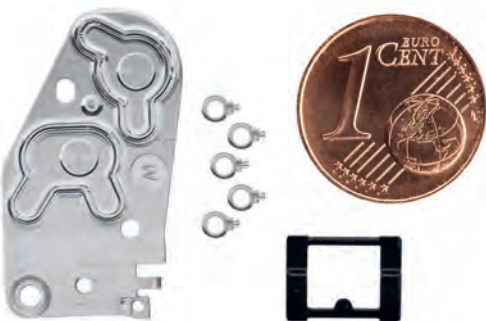
Injection molding

Latest injection molding technologies

Sustainable pharmaceutical, diagnostic and medical products unite a plus in functionality and design quality with optimized production costs – a performance that is only possible through innovative production technologies. This is why Gerresheimer offers modern injection molding technologies such as multi-component injection molding (2-K, 3-K), insert molding, turning stack mold technology, water injection and internal gas pressure, sandwich technology, injection embossing, in-mold decoration, thin wall injection molding, and micro injection molding.

Micro injection molding

Miniaturization is one of the most important technological trends. More and more functions are integrated in medical devices, which means that the components have to become smaller and smaller and the precision requirements higher and higher. In order to meet these challenges, we use the latest injection molding technologies in our production such as micro injection molding.



Micro injection molded parts of an infusion pump



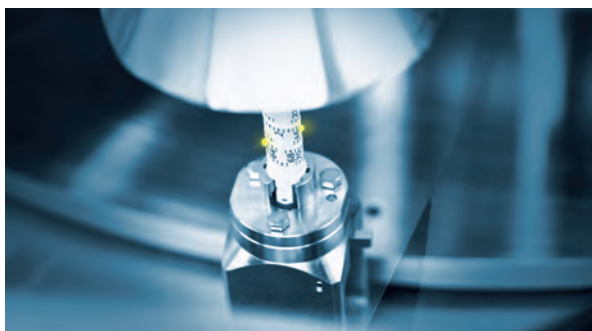
Micro injection molding system in a clean room in accordance with ISO 14644-1 ISO class 8



Finishing

Sophisticated product finishing

Naturally, we also carry out the surface decoration of all components in accordance with your individual ideas. We complete finished products, for example, through printing, laser marking, metallizing, lacquering, sleeving, and many other decorating methods. Large-scale product finishing is subjected to the same quality requirements applied to the production of individual component assemblies: upon request, we integrate camera systems into the decoration line to ensure the immaculate quality and precise positioning of printed images and labels. This way, we can be sure that your desired design is implemented with high quality and cost efficiency.



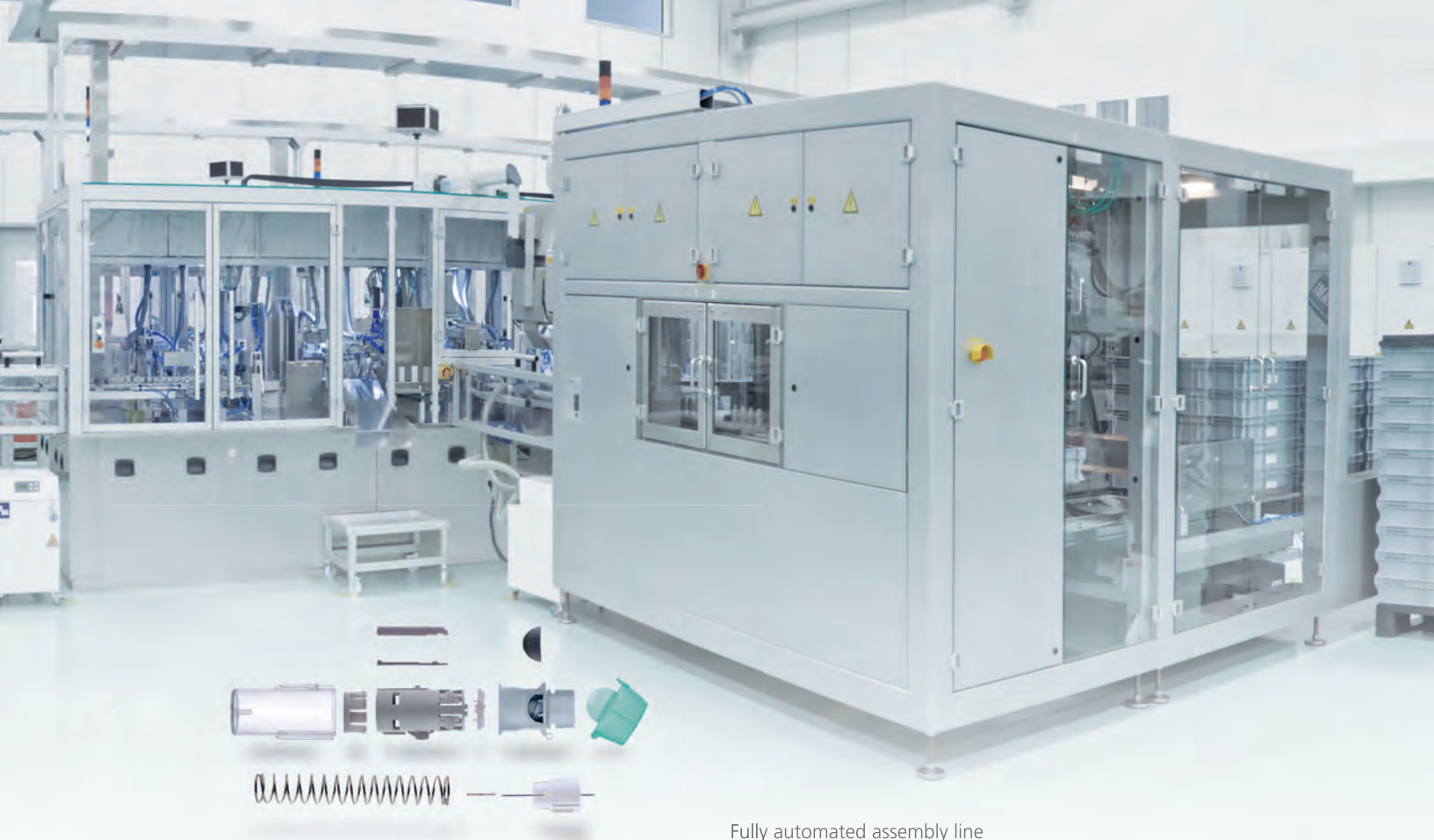
Laser marking of a plastic part for an insulin pen

Product-specific production steps

On behalf of our customers, we assume responsibility for product-specific manufacturing steps like, for example, the filling of the dilution solution required for point-of-care tests or the loading of point-of-care test housings with the test strips under climate, temperature and air humidity conditions specifically configured for this process. In the case of inhaler, we ensure the reliable functioning of the modules in that we improve gliding properties through the dispensing of Vaseline with individually adjustable dispensing valves in the assembly system. For an applicator, we apply Teflon on the contact surface for the placement of a permanent implant.



Vaseline metering with individually adjustable metering valves to improve gliding properties.

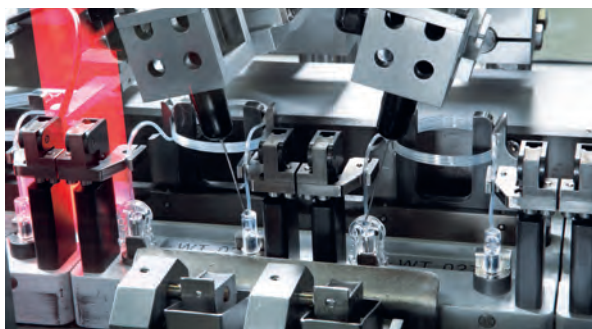


Fully automated assembly line

Assembly

Sophisticated joining and bonding technology

For the production of drug delivery systems, medical and diagnostic products, in addition to clean room production, we use sophisticated joining processes like the laser welding of plastic and metal parts, ultrasonic and vibration welding, as well as thermoforming and cold calking. We possess the know-how for the gluing of sophisticated plastic and metal parts or tubes. For an infusion set, for example, we glue a tube with a coupling part and then harden the glue with UV light. A subsequent 100% check of whether the glue has been correctly dispensed, and an additional test to determine whether the tube also still provides the correct volumetric flow after gluing is carried out directly in the fully automatic system.



Gluing of tube and coupling part with subsequent flow inspection

The most cost-efficient assembly solution for every product

For the assembly of plastic parts, assembly units and complete devices we offer you both modern, fully automatic assembly technologies and semi-automatic or manual assembly, which are primarily more affordable for smaller series. Our assembly lines ensure that the products have the best surface quality due to surface-preserving assembly and a visual inspection for damages on visible parts within the assembly system. A 100% in-process control of the assembly steps, the parameters that are critical for quality as well as the assembly, and product functions is performed with the help of several different camera systems and control stations in the assembly system. Gap-free documentation of the assembly processes ensures the traceability of all batches.



Manual assembly of an inhaler in Dongguan City, China

Pharmaceutical Packaging and Filling

Assembly of electronics

As an expert in combining plastics with metal, we can also, if desired, take over the electronics assembly. We integrate electronic counters in the drug delivery devices for the dosing, atomization actuators, and various sensors. We provide disposable laboratory articles with RFID chips, because the traceability of tests and providing of information of the analysis devices being tested, are gaining increasing importance. For the assembly of electronics, we create our own clean rooms, which are also equipped with a special ESD protective floor for preventing static charge. Special camera tests in the assembly unit ensure the correctly positioned insertion of circuit boards, the damage-free positioning and snap-fitting of punch parts and the correct position of switches. A gap-free in-line function test at the assembly system rounds off our range of services.



Assembly of electronics into an inhaler

To be able to offer you a complete solution, which does not only include injection molding, assembly, packaging, and finishing, but the loading of the drug as well, we created a pharmaceutical packing and filling area at our location in Pfreimd.

Sterilization, Packaging, and Global Logistics

Product-specific packaging options

Gerresheimer offers you many different packaging options such as packaging in blisters, in a transport tray (disposal or reusable), air-tight aluminum bag (moisture protection), sterile packaging, in disposable and reusable packaging, in a Tyvek bag (ethylene oxide



Lab disposables with RFID chip for the tracing of tests



Pharmaceutical filling area at the facility in Pfreimd, Germany

and gamma-sterilizable, steam-sterilizable up to 125°) or in a special clean room bag. With the packaging, too, we pay attention to fulfilling the strict requirements of the pharmaceuticals and medical technology industries for quality and cleanliness. Our systems ensure that the product is carefully placed in special transport trays. The use of specially washed trays thereby adjusts the number of particles to the prescribed specification. Like production and assembly, packaging at Gerresheimer can also take place in the clean room.

Packaging including original seal and sterilization

Upon request, we can also sterilize your product in collaboration with our partner. We package an infusion set in a blister pack, for example, seal it with a Tyvek film and print the film. These finished individual packages are placed in boxes of 10, and the package insert and separating strips are added. A robot applies the label on the front and the back and secures the final packaging with a tamper-evident closure. Then, the completely packaged products are sterilized with ethylene oxide (ETO).

The gas-permeable Tyvek film makes it possible for the ETO to permeate the packaging and to subsequently release the gas again.



Individual packages are placed in boxes of ten, a package insert and separating strips are added.

Packaging in transport trays



Certified Quality

Qualification and validation for international markets

“Quality in plastics” is our philosophy. This is why Gerresheimer Medical Systems uses a globally standardized quality management system that is certified in accordance with ISO 9001, EN ISO 13485, DIN EN ISO 15378 and an environmental management system according to DIN EN ISO 14001. In addition, we comply with the relevant FDA guidelines, GxP and normative product requirements (such as the labeling of medical products). This also means that, in addition to the validated production processes, our buildings and clean rooms as well as the warehousing are qualified and validated in accordance with clearly defined quality criteria. For specific products, we meet additional requirements or standards in our various facilities.

Certificate of accreditation as overseas manufacturer

In cooperation with our customers, the Gerresheimer production facilities Pfreimd (Germany), and Dongguan City (China) were accredited as manufacturers of medical products for the Japanese market. The certificates relating to the accreditation as “overseas manufacturer” in Japan are valid for five years.

Example of excellent performance: FDA inspection

Our facility in China, Gerresheimer Medical Plastic Systems Dongguan Co., is an FDA-inspected medical device manufacturer for the production of an inhaler used to treat cystic fibrosis. Within the context of a drug approval for an inhaler on the US market, the entire value creation chain was scrutinized according to stringent standards. This included the purchasing of the rubber and metal parts, the injection molding, the assembly and testing, the laser printing, and the tamper-evident closure.

Successful inspection by the Brazilian Authority of Health Monitoring

Our facility in Pfreimd (Germany) successfully passed an inspection by the Brazilian National Authority for Health Monitoring ANVISA (Agência Nacional de Vigilância Sanitária).

Assistance with the registration of product files

We also handle for our customers, both the qualification in accordance with GMP and FDA guidelines and the preparation and submission of the documentation for medical products and pharmaceutical primary packaging means (for example DMF type III, EU file).



Validation along the entire value creation chain

Our validation approach follows the classic V model and comprises all the phases from DQ to PQ. Each individual production process is validated to ensure that the sum of all steps leads to the desired, reliable production sequence. The tests determined by our quality planners in the Technical Competence Center (TCC), specified in the test plan, and verified during the validation, are carried out as part of the product development process in collaboration with the production from incoming goods and process testing to the approval testing.

Systematic error processing

Our Quality Management is based on a sound corrective and preventive action (CAPA) system combined with systematic problem solving according to the Kepner Tregoe methodology. A binding change/control process ensures that changes do not have a negative effect on the qualification status of equipment or the validated status of a process.

To handle complaints and deviations, define corrective and preventive actions, and their follow up, we use an electronic workflow management system, i. e. SAP QIM, which fully meets the requirements of 21 CFR part 22. Comprehensive documentation is prepared for all quality assurance measures, which are also included in the respective customer certificates.

Continuous improvement by the Gerresheimer Management System (GMS)

We want to become better all the time, for our customers and for human health. Our key for this is GMS: Gerresheimer Management System. The Gerresheimer Management System (GMS) forms the basis for the continuous improvement of all business processes in the Gerresheimer Group. GMS includes and describes the most important methods, processes, and regulations of a facility in a systematic and standardized form, thereby creating transparent, binding standards.

Our criteria for success in terms of customer satisfaction are the goals of the GMS: top-quality products and services, minimum cost, adherence to delivery times, product and process innovation, elimination of waste, continuous improvement, acquisition, development, and preservation of competency and consistent inclusion of all employees.



Customized Solutions Made from Glass and Plastics

DRUG DELIVERY DEVICES



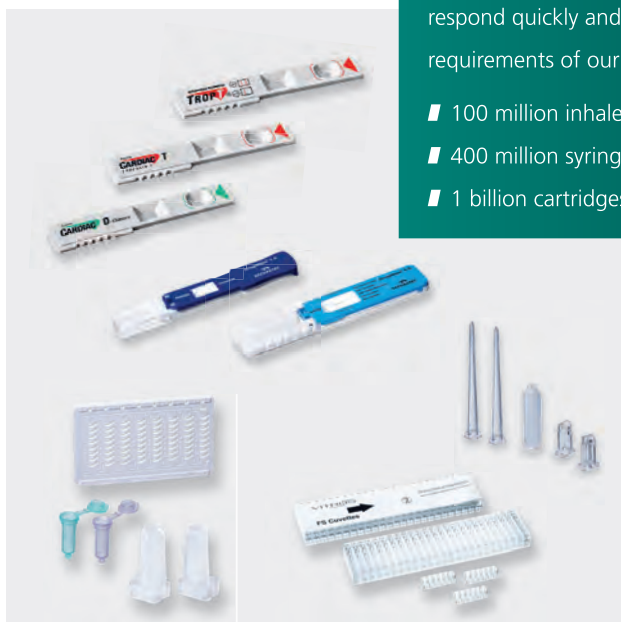
PRIMARY PACKAGING



MORE THAN 70 YEARS OF EXPERIENCE

With more than 70 years of experience in glass forming and processing of plastics, and approximately 2,900 employees, we respond quickly and flexibly to the specific requirements of our customers.

- ▄ 100 million inhaler per year
- ▄ 400 million syringes per year
- ▄ 1 billion cartridges per year



DIAGNOSTIC PRODUCTS



MEDICAL PRODUCTS

Business Unit Medical Systems

Plastics and glass under one roof

Our most important goal is to offer our customers customized solutions. Whether we use glass or plastics as the material is of lesser importance. The differentiation between the two materials in any case hardly plays a role anymore. Prefilled syringes or cartridges made from glass are used increasingly in drug delivery devices made from plastics. As a consequence, both products should be developed and produced in a highly coordinated manner.

This is why Gerresheimer AG bundled its competency for both of these primary materials at the end of 2013 under the roof of the Medical Systems business unit. Here, the glass specialists from the Center of Excellence for syringes at Gerresheimer Bünde, work hand in hand with the plastics experts in the worldwide Technical Competence Centers. In the new constellation, we have access to an even broader experience base in order to develop innovative concepts for the growing medical technology and pharmaceutical challenges of today.

Premium quality for our customer's products

Gerresheimer Medical Systems produces innovative and groundbreaking products in the segments drug delivery devices, primary packaging, diagnostic and medical products. We produce ready-to-fill syringes made of glass and plastics, glass cartridges and ready-to-fill vials as well as customer-specific, injection-molded plastic assemblies all over the world. For the global players of the pharmaceutical and medical technology industry, we produce inhaler, pen systems, auto-injectors, laboratory disposables, point-of-care tests for patients in medical practices or hospitals, lancing devices and lancets, infusion sets, micro-infusion devices, catheters and much more.

As experts for combination products, we offer our customers the opportunity to develop, together with our glass and plastic specialists, complete application systems that are geared toward specific active ingredients and application areas.



Easy Handling and High Functional Reliability for Drug Delivery Systems

Drug delivery systems produced by Gerresheimer

Our systems comply with all requirements of up-to-date pharmaceutical primary and secondary packaging. We cover the entire spectrum of delivery types: inhaler, syringes, and syringe components, pen systems, and auto-injectors. Together with our customers, we develop the optimal primary and secondary packaging for all types of active pharmaceutical substances. So we manufacture products that can be dosed more easily, provide convenient and user-friendly handling to patient and transport the active substance quickly and efficiently to where it is needed.

Inhaler

In close cooperation with leading pharmaceutical companies, Gerresheimer Medical Systems has been globally developing and producing powder inhaler, capsule inhaler, and nebulizer for the treatment of respiratory diseases such as Asthma, COPD (Chronic Obstructive Pulmonary Disease), and cystic fibrosis for more than 20 years. With our annual production of over 100 million inhaler, we are a leading specialist in the area of customer-specific drug delivery devices for inhalation therapy. Our complete service also includes the appraisal of drug delivery systems and the evaluation of systems together with their entire documentation (e.g. device master file) as the basis for the approval of the product.



We produce powder inhalers, capsule inhalers, and nebulizers for leading pharmaceutical companies.

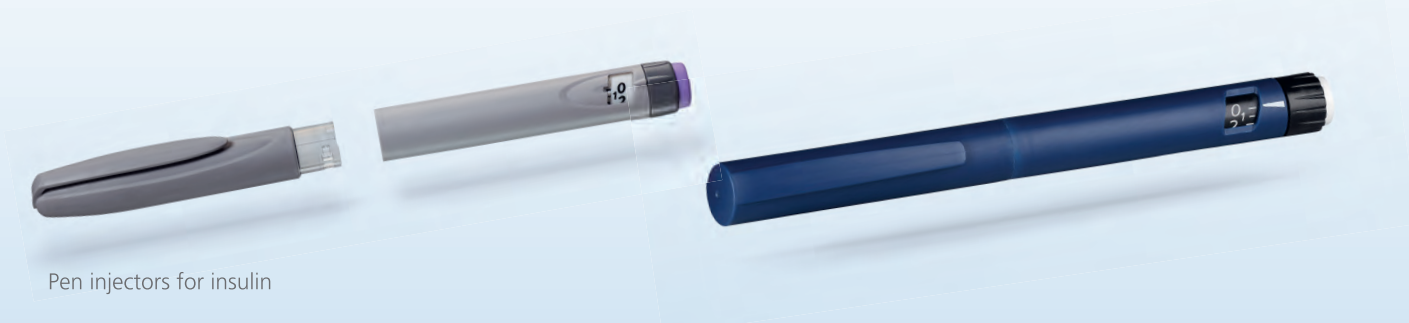




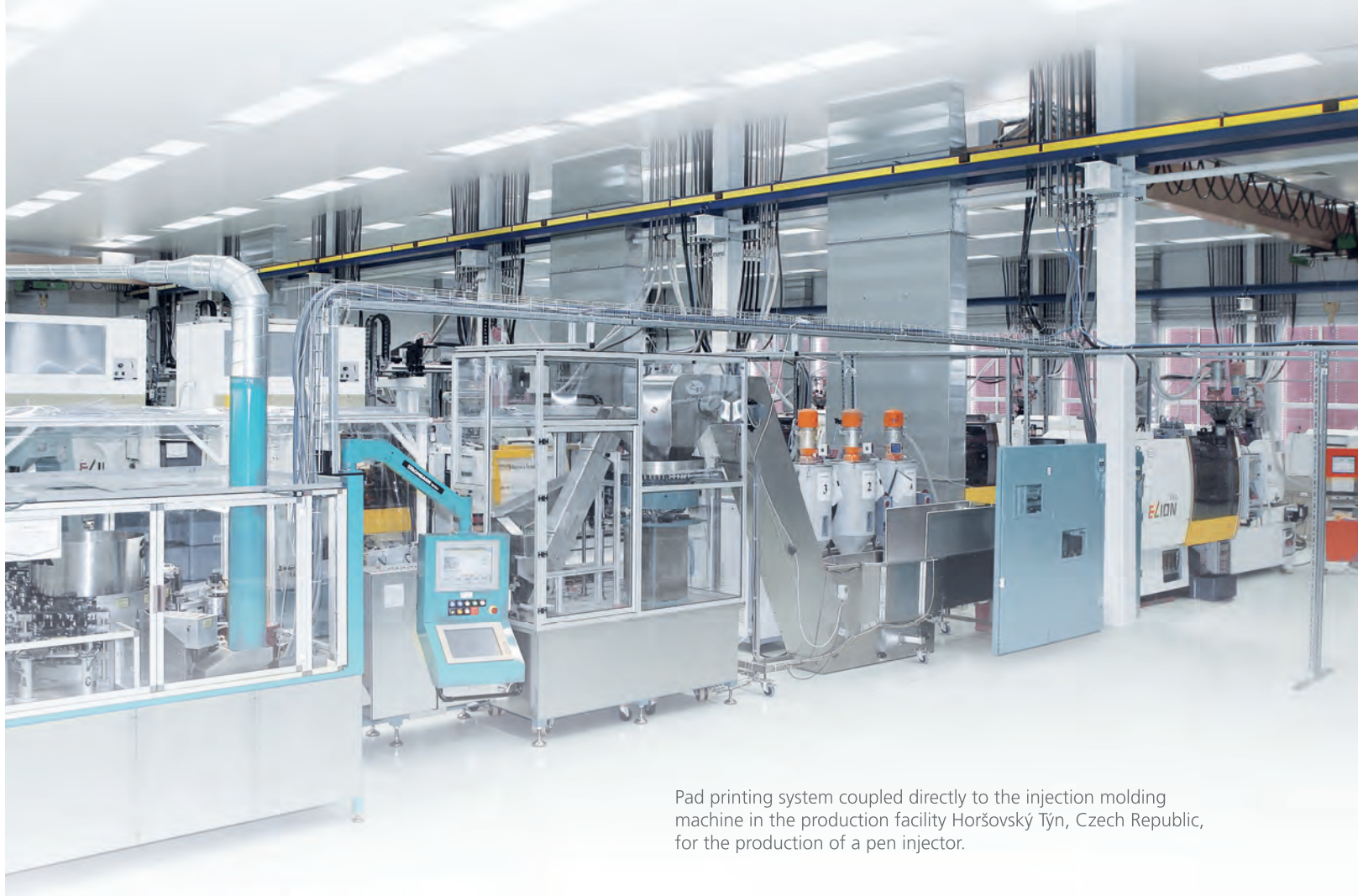
Reusable pen injectors and disposable pens

In the product segment of pen injectors for insulin and other hormones, our core competencies are both high-quality, reusable pen injectors, as well as cost-effectively produced disposable pens – including the glass cartridge. We produce more than 350 million disposable pens annually. Our highly automated assembly processes and pad printing systems directly coupled with the injection

molding machine, ensure the most cost-effective production. With regard to the production of high-quality, reusable insulin pens, their acceptance in the day-to-day life of patients, also depends on an attractive design, we use the entire portfolio of our technological know-how: the laser welding of metal parts, laser welding and laser labeling of plastic parts, and lacquering processes meet the highest technical and visual quality requirements.



Pen injectors for insulin



Pad printing system coupled directly to the injection molding machine in the production facility Horšovský Týn, Czech Republic, for the production of a pen injector.

Injection systems

Whether you need components for needle-free injection systems, safety syringes, tamper-proof closures or auto-injectors, in Gerresheimer Medical Systems you have found an experienced partner. We actively address dermatological questions such as penetration behavior and pain development and use this knowledge for the development and production of sophisticated injection systems.



Auto-injector and syringe components

Primary Packaging from Glass and Plastics

Gerresheimer Bünde is our Center of Excellence for prefillable glass syringes, glass cartridges and ready-to-fill vials. Here, we develop and produce both standard products and customized product solutions. The strictest requirements for glass bodies are met on highly precise production systems. These are planned and built by our in-house engineering department and fulfill the most modern requirements.

Cartridges

Our program comprises cartridges of the glass type I and a size of 3.0 ml (other formats upon request). By using the latest production technologies and state-of-the-art camera inspections, we guarantee the highest precision and quality. Our production lines that work with optical inspection

systems perform 100% of the control of the dimensions.

Other visual control systems in our high-quality facility check the cartridges for any cosmetic defects and verify the perfect fusing in the bottom area with the help of special cameras.

Glass Syringes

Our product range for syringes comprises glass syringes in bulk and "ready-to-fill" format with a filling volume ranging from 0.5 ml to 5.0 ml, Luer cone and Luer lock systems as well as needle syringes. Innovative syringe components, various siliconization options, syringes with reduced tungsten content, as well as all types of printing possibilities complete our product spectrum.



Glass and plastic syringes



Clean room production of ready-to-fill syringes in Bünde, Germany

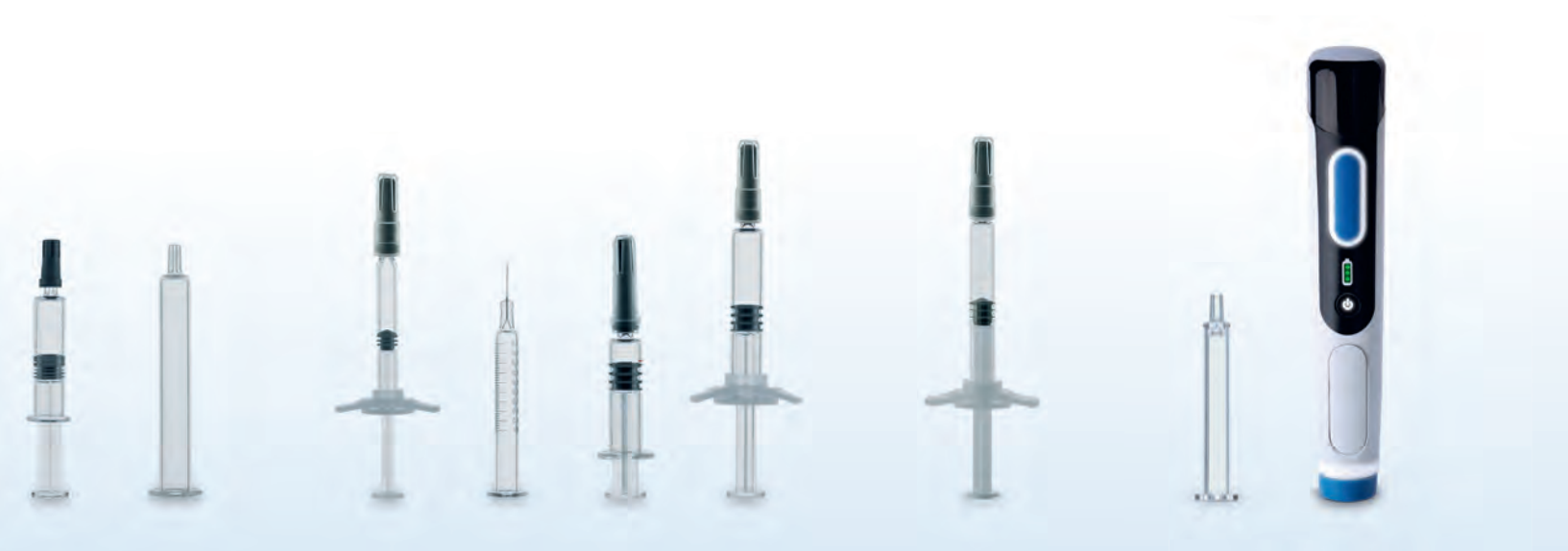
Primary packaging and drug delivery device from one hand

The plastic experts in our Technical Competence Centers in Germany, the US, and China work hand in hand with the glass specialists of Gerresheimer Bünde and perfectly coordinate the primary glass packaging and the respective drug delivery device. With regard to pen systems and cartridges, for example, we make sure that impression forces are optimized and that the cartridge is perfectly positioned in the pen system. Pre-filled syringes are used increasingly in auto-injectors or provided with safety systems to protect against puncture injuries.

Polymer Syringes

Another convincing example in the cooperation of our experts for syringes and plastics is our range of customer-specific developed and produced polymer syringes.

Under the tradename Gx RTF® ClearJect® we offer a standard range of ready-to-fill polymer syringes made from COP for sensitive active pharmaceutical ingredients.



For the needle-free automatic injection system from Portal Instruments, we produce a cartridge-like container made of the high performance polymer COP.



Disposable Diagnostic Products

Disposable laboratory products for the entire sample throughput

Whether disposables for sample preparation, reagent vessels and tips for sample processing or cuvettes and micro well plates for sample analyses – we develop and produce disposables for the entire sample run in laboratories.

Consistently high quality and identical reproduction are absolutely necessary for laboratory disposables made from plastics, because the slightest deviation can, for example, impair the results of visual and chemical analysis processes in cuvettes. With the help of a safe selection of materials and high-cavity molds that are designed for a clean room

production, we create the conditions necessary to produce these sensitive products in perfect quality. Large quantities require highly automated production processes. We develop and build product-specific complete solutions for this purpose. Handling robots that are directly coupled with the injection molding machine, nest-specific removal systems, test systems, for example, for testing the seal, as well as automated assembly and packaging systems ensure efficient production. This way, Gerresheimer Medical Systems is able to produce billions of cuvettes.



Laboratory disposables to prepare, process, and analyze samples



Reliable point-of-care tests

In the area of point-of-care tests, the name Gerresheimer Medical System stands for full service: whether drug detection, pregnancy tests, detection of emergency parameters, or allergy tests. Whether used in doctor's office or the analysis device in the lab: We produce your complete point-of-care test, including assembly of test strips or filling of the necessary diluting solution.

At the start of the development, we select the best material to suit the required flexibility of the point-of-care test. Our point-of-care experts then develop a

customer-friendly housing design that is easy to handle. The optimal joining technology (snap lock, gluing, or welding) and the optimal functional support of the membrane (pressure points) includes the development of a user-friendly and safe point-of-care test. Due to the extremely high contamination sensitivity of point-of-care tests, we offer our customers the entire production and assembly process in the clean room according to ISO 14644-1 ISO class 8 – including sealing in an aluminum pouch offering maximum protection prior to shipping.



Point-of-care tests to be used in doctor's office or in the analysis device in the laboratory



Medical Products

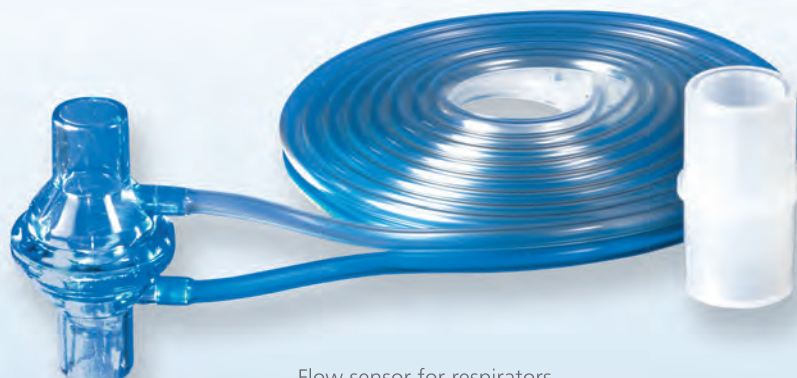
The tailored production solution for every product

Irrespective of the number of units and the requirements of the medical product, we offer our customers a tailored production solution. In addition to the fully automated mass production of medical products, we also offer the manual and semi-automated small batch production of complex, technically sophisticated injection molded products. In our small batch production, we have our own production facilities (injection molding machines, project-specific assembly systems such as joining robots, gluing devices, or ultrasound welding systems) as well as a clean room according to ISO 14644-1 ISO classes 7 and 8 or respectively GMP classes C and D are available.

As a diabetes specialist, we cover the entire spectrum of diabetes products. We develop and produce products for diabetes diagnostics such as lancing devices and lancets, as well as products for treating diabetes. In this area as well, we have significant experience due to the production of infusion sets and pen injectors, including glass cartridges, for the administration of insulin and other hormones.



Successful FDA inspection: the production of the CentriMag® blood pump



Flow sensor for respirators

Lancing devices and lancets

Together with one of the leading diagnostic companies, we develop and produce the fifth generation of lancing devices and lancets for blood sampling. In order to enable low-pain blood taking, we have, together with our customer, optimized nearly all components of the lancing devices the past 15 years. Starting with increasingly fine needles, which hardly injure tissue and ensure quick wound healing through a precise feed of the lancets to the ergonomic optimization of the lancing devices,

all innovations are aimed at increased user-friendliness and thus at an improvement in compliance. Gerresheimer is your specialist in the matter of needles. Due to our many years of producing billions of coated needles and cannula, we have gathered comprehensive know-how for the coating of both. We overmold even the finest needles (0.3 mm) fully automatically, individually and in only one work step with a hard-soft component.



Together with our customers, we have already developed and produced five generations of lancing devices.

Infusion sets

In diabetes patients who obtain insulin from a pump, an infusion set connects the insulin pump with the body. Together with a leading diagnostic company, Gerresheimer developed a solution for this that consists of an air-permeable, skin-friendly band-aid and a needle housing with guide needle and cannula. In order to meet the different needs of patients, the set is available in versions with a flexible Teflon cannula for high wear comfort or an extra-thin steel cannula that is pain-free, as well as with a fixed or detachable insulin pump. Particularly innovative is the design of the needle and cannula in the Teflon cannula product version. A tube made from very soft fluoride

ethylene propylene (Teflon FEP) is reformed into a soft cannula, pulled over the needle and then coated.

Another challenge is the gluing of the set's sophisticated plastic and metal parts. The fully automated production system checks all parts as to whether the glue is correctly dosed and was hardened with UV light and whether the tube provides the correct flow even after the gluing process. Gerresheimer was responsible for all the project steps from the design concept and the development, the user tests of development samples, the mold and plant construction, as well as the procurement of all purchased parts to mass production.



Infusion set with flexible Teflon cannula and detachable insulin pump



Infusion set with flexible Teflon cannula and fixed insulin pump

Liquid Drug Delivery Solutions

Self-administered by patients

Our competence center for micro pump technology in Olten (Switzerland), Sensile Medical, has developed a novel micro volumetric rotary piston pump which forms the heart of our micro-infusion pump devices. We offer a broad range of customer specific platforms for drug delivery and dosing solutions. The devices manage the controlled small to large volume subcutaneous delivery of respective medicines for self-administration by patients. The pump design sets new standards in liquid drug delivery by:

■ Safety and Reliability

The SenseCore micro volumetric rotary piston pump technology ensures flow in one direction allowing double safety against free flow

■ Cost efficiency

The pump technology requires lowest number of polymer-based components, hence high cost effectiveness

■ Accuracy

The innovative device architecture allows flexible and precise flow profiles as well as bolus options

■ Scalability

The SenseCore technology manages scalable volumes ranging from 50 µl over 24 hours to 5 ml per minute

■ Disposable and Reusable Parts

The medical devices are comprised of a disposable and reusable part thus minimizing waste and reducing costs

■ Connectivity

Bluetooth wireless enables easy connection of the device to apps or other digital services



Micro volumetric rotary piston pump –
The SenseCore Technology

Modularity and Flexibility

Micro-infusion pump devices

Therapies are diverse and must often meet a variety of patient needs. Whether a medical device is only used several minutes or for 24 hours – we develop individualized solutions. Our products are adaptable for different therapies and flexible to primary packaging (type, size, fill volume). They are characterized by highly accurate and predictable delivery, easy handling steps and various safety features.

Patch Pump – Small Volume up to 5 ml

- Adjustable flow patterns over hours with bolus option
- Adheres to the skin and has an integrated auto-inserter for the needle
- The needle mechanism ensures an easy, discrete needle insertion and is automatically inserted prior to drug delivery
- **Primary drug container: Standard cartridge**



Patch Pump – Large Volume up to 20 ml

- Delivery from minutes to hours
- Potential usage of standard vials as primary packaging. Eliminates the need for the costly and time-consuming development of a prefilled cartridge and avoids the associated development and regulatory risks
- Fully automated needle insertion and retraction
- **Primary drug container: Vial, cartridge**





Belt worn pump up to 20 ml

- Adjustable flow pattern over hours with bolus option
- This device is worn off-body (for example belt worn or in a body bag)
- A luer connector enables the delivery of the drug product via a standard infusion set.



Fully customized solutions for dedicated branding and differentiation

The first wearable micro-infusion pump device under the brand name D-mine® was developed for EVER Pharma. It recently received European CE certification and has already been launched in several EU countries. The compact, patient-friendly infusion pump device is used for the continuous subcutaneous administration of apomorphine to treat advanced stages of Parkinson's disease. This device with a micro pump gives Parkinson's patients greater independence in their day-to-day lives.

The compact, user-friendly device contains Sensile Medical's protected and straightforward micro-rotation pump technology taking human factor study results into

account. Parkinson's patients typically are facing difficulties to control muscular movements and therefore appreciate the device's ease of use with:

- **Interactive colour display and Data storage**
Keeps users informed about device activity and enables to monitor patient adherence
- **Docking station designed for specific patient group**
Easy handling for Parkinson patients to prepare the device for use and with recharging unit for battery
- **Patient-centric adjustable delivery rates**
Healthcare professional sets patient specific 24 h basal rate pattern and bolus options

Are you interested in state-of-the-art pump devices for controlled, subcutaneous administration of your liquid drug formulations? Our package of services can be the solution you always have been looking for:

- Testing of your active ingredient with our micro pump
- Adapting the pump for your active ingredient
- Develop a dedicated design for your device
- Injection molding of plastic parts for the device
- Assembly
- Printing
- Packaging

We can also offer you the necessary primary packaging for your device – everything from one supplier.





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