GERRESHEIMER
Medical Plastic Systems

www.gerresheimer.com

Medical Plastic Systems

We turn visions into products ready for market

Clean room production to ISO class 8 at our production site in Pfreimd, Germany.

Gerresheimer Medical Plastic Systems
All benefits at a glance

- Full service – from development through to logistics
- Global player – worldwide production sites and clean room capacities
- Concentration of technical expertise in our international Technical Competence Centers in Germany and the USA
- In-house design expertise
- In-house Product and Process Development
- In-house Mold making
- In-house Automation Engineering
- Innovative production technologies
- Competence in validation and certification and highest quality standards

Quality for medicine: More safety for people – better quality for life

Gerresheimer is one of the leading specialists for the production of high-quality glass and plastic products for the international pharmaceutical and healthcare industry. We offer a wide range of products and services, from pharmaceutical vials right through to complex drug delivery systems such as syringe systems, insulin pens and inhalers for reliable and safe drug dosing and application. In cooperation with our partners we develop concepts that set new standards and serve as a model for the entire industry. Our company group with 47 production sites and more than 11,000 employees in Europe, the US, Central America and Asia generates revenues of about EUR 1 bn. The systematic consolidation of our strong market position is based on state-of-the-art technology, technically sound innovations and strategic investments.

The Medical Plastic Systems Division focuses on activities in the plastics segment. For more than sixty years, we have been supplying special injection molded and assembled plastic systems to renowned customers from all parts of the world. Gerresheimer's Medical Plastic Systems Division employs more than 1,700 people and is established as an important system supplier to global players in the pharmaceutical and medical technology segments.

As a full service provider Gerresheimer Medical Plastic Systems performs all levels of the value-added chain from planning up to the CE-certified point-of-sale product. Product design, product development, manufacturing equipment development, mold making, automation engineering, small and large scale production according to FDA/GMP, post-production finishing, manual, semi-automated and fully automated assembly, pharmaceutical packaging and filling as well as packaging and freight management – we are your one-stop shop.

As a result of our long experience we are very familiar with the world of our customers. We speak their language, know their working conditions and can respond to their wishes individually. Furthermore, we constantly deal with current medical issues. The intense dialogue with pharmacists, biologists, institutes as well as academies and colleges enables us to react early to important innovation potentials.

If you choose Gerresheimer Medical Plastic Systems you choose the technological leader, you choose a flexible company which is able to decide quickly and puts the wishes of the customer in the center of thinking and acting. For highest quality.

From left to right: Novel press-and-inhale multidose DPI produced for Almirall, Analyzer with test cartridge HbA1C.

Qualification and validation for international markets

We aim at delivering quality in plastics. Therefore, Gerresheimer Medical Plastic Systems operates a quality management system to international standards, which is certified to DIN EN ISO 9001, DIN EN ISO 13485 and DIN EN ISO 14001. At the same time, we implement a set of locally significant specifications and standards. Moreover, relevant FDA guidelines and different GMP as well as standards-related product requirement (such as labeling medical products) need to be taken into account. This means, we do not only certify and validate production processes, but also production halls and clean rooms as well as storage facilities to clearly defined quality criteria.

Our Technical Competence Centers (TCC Germany/USA) are responsible for centralized international quality management and validation of our processes; implementation is carried out at individual sites by means of standard quality management tools such as extensive risk analyses, FMEA and QFD (Quality Function Deployment) so as to methodically and systematically assess customer requirements and implementing them into process and test planning. This way, the TCC delivers mature, viability-checked products and production resources to our international production sites.

At Gerresheimer Medical Plastic Systems, quality management is a decisive cornerstone of the corporate Gerresheimer Management System (GMS) with the objective of ongoing improvement of productivity, quality and cost awareness. GMS is comprised systematic set corporate methods, processes and rules for creating transparent and obligatory standards. Apart from methods and tools, GMS offers core systems for staff members, quality and material management. All Gerresheimer facilities undergo regular GMS-based audits.

Excellent quality out of one hand: plastic parts, test strip and packaging. Short ways ensure highest quality at all stages of the value-added chain.

An example: Gerresheimer Medical Plastic Systems produces complete Lateral Flow Tests and the test strip production is located in the own laboratory.

Sanofi ClikSTAR® – a high-quality product made by Gerresheimer Medical Plastic Systems.

Validation and certification

- Quality management according to
  - DIN EN ISO 9001:2008
  - DIN EN ISO 13485
  - DIN EN ISO 14001
  - FDA Guidelines
  - 21 CFR Part 11
  - GMP
- Certificate of accreditation as overseas manufacturer
- Manufacturing license according to the German Drugs Law
- FDA inspection without observation for the production of a medical product with direct blood contact
- Support for the registration of product files

Certified quality

Certificate of accreditation as overseas manufacturer

In cooperation with a leading diagnostics company, the Pfreimd facility (Germany) and Dongguan City (China) were accredited as manufacturers of medical products for the Japanese market. The certificate of accreditation as overseas manufacturer is valid for five years until January 22, 2013.

Manufacturing license according to the German Drugs Law

Gerresheimer Medical Plastic Systems has a manufacturing license according to the German Drugs Law (AMG) for pharmaceutical assemby to AMG.

Example of excellent performance: FDA inspection

A successful inspection by the FDA confirmed that Gerresheimer Medical Plastic Systems regarding performance and quality has acquired a first-class position among all companies worldwide manufacturing medical-technological products. The audit covered the complete value-added chain of the production of the CentriMag® blood pump system. Gerresheimer Medical Plastic Systems was responsible for injection molding, assembly, testing and sterile packaging of the blood pump in an ISO class 8 clean room as well as hygiene monitoring in compliance with GMP class D. The audit included a production observation by an FDA investigator and the customer Levitronix. The pleasant result: No observations – zero-variation operation and thus classification as FDA-Inspected Device Manufacturer.


CERTIFICATE

DQS Medizinprodukte GmbH

GERRESHEIMER

Gerresheimer Regensburg GmbH

has implemented and maintains a Quality Management System

EN ISO 13485 : 2003 + AC : 2009

Quality lab and test field

We increase the quality of our products by integrating our quality tests into the value-added chain. Our quality assurance department operates an in-house quality laboratory within the TCC, which combines the material testing laboratory and the test bay for incoming goods control and the verification of component functions.

Gerresheimer Medical Plastic Systems also performs the examination of original materials and products on extractables. This examination is also reasonable regarding primary packaging materials for medical products because plastics may contain undeclared additives which might be toxic or react with other substances when administered. Such substances might discharge after a certain time, mix with the agent of the drug and thus be consumed by the patient. Gerresheimer Medical Plastic Systems is dedicated to execute such analyses within a release check and is competent to do so. We perform this examination with high-resolution analyses and the corresponding expertise knowledge.

quality

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

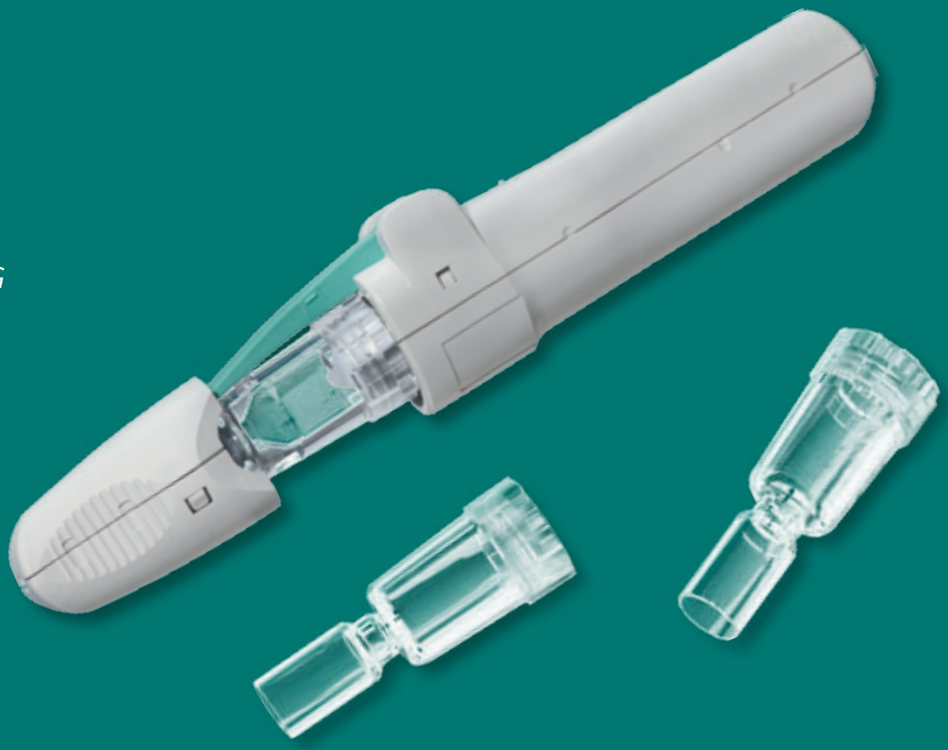
»Our aim is that our customers can rely on receiving the products in good quality on the desired date. After all the health and possibly even the life of the patient is at stake.«

PHARMACEUTICAL

Alexza Pharmaceuticals
ALK-Abello
Almirall
AstraZeneca
Bayer Schering Pharma AG
Boehringer Ingelheim
Bristol-Myers Squibb
Teva
Meda Pharma
Novartis
Novo Nordisk
Pfizer
Sanofi
Zogenix, Inc.

MEDICAL TECHNOLOGY

Aesculap
Bayer Crop Science
bioMérieux
Bio-Rad
British BioCell International
Coloplast
CSL Behring
DiaSorin
Ethicon EndoSurgery
Gambro
Hamilton Medical
Merck
MRC
Nunc
Ortho-Clinical Diagnostics
Phadia
Philips Healthcare
Qiagen
Roche Diagnostics
Securetec
Siemens Healthcare
Swiss CI
Thermo Fisher
Thoratec
Trinity
Verax



Components for the DosePro™ needle free delivery system for Zogenix, Inc.

Business Areas

Pharmaceutical

- Inhalation
- Pen Systems
- Autoinjectors
- Injection
- Transmucosal
- Oral

Medical Technology

- Laboratory diagnostics
- Molecular diagnostics
- Point-of-care testing
- Diabetes Care
- Surgery
- Urology
- Dialysis & blood therapy

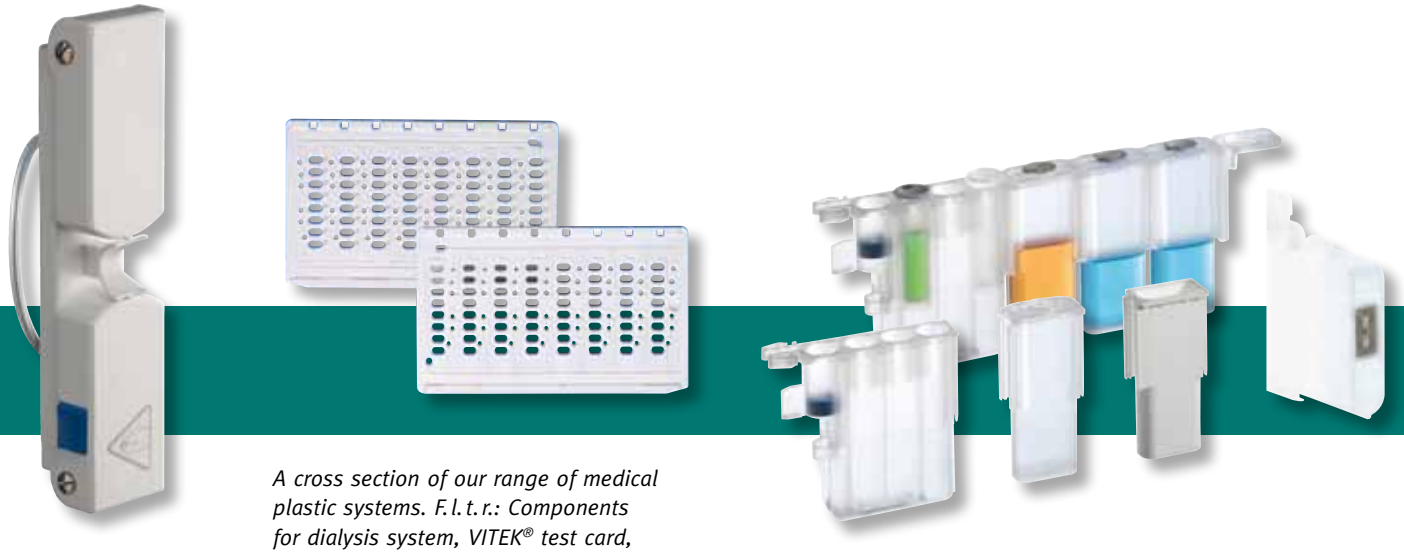
Premium quality for our customers' products

Gerresheimer Medical Plastic Systems manufactures innovative and groundbreaking products in the segments Pharmaceutical and Medical Technology. Our core area of competence lies in fully automated large-series production as well as in the manual and partly automatic small-series production of complex and technically demanding products made of several plastic components. The combination of plastics and metal for cannulas for implants, needles for lancets or springs for driving elements in systems as well as the production of very small parts with high-cavity molds are part of our know-how.

For the pharmaceutical industry we produce complex drug delivery systems that work with several systems to transport the active substance into the body precisely. For leading medical technology enterprises we produce lancing devices, lancets and disposables for a variety of analysis systems in laboratories and surgeries, quick-tests for patients in surgeries or hospitals as well as disposables for dialysis, catheter and surgical devices made from plastics.

The best criterion: Satisfied customers

Well-known customers from all around the world rely on our absolute demand for quality, our all-inclusive service and on our decade-long experience. Numerous awards we received from well-known companies give proof of highest customer satisfaction.



A cross section of our range of medical plastic systems. F. l. t. r.: Components for dialysis system, VITEK® test card, reagent rack with RFID chip.

Easy handling and high reliability of drug delivery systems

Drug delivery systems by Gerresheimer Medical Plastic Systems comply with all requirements of up-to-date primary pharmaceutical packaging. We cover the entire spectrum of delivery types: Administering the active substance via pulmonary inhalation, through the skin, via the mucous membranes or orally. Jointly with the customer we develop optimum primary and secondary packaging for the most diverse active substances. So we manufacture products that can be dosed more easily, provide very convenient and user-friendly handling to the patient and transport the active substance quickly and efficiently to where it is needed.

With Gerresheimer Medical Plastic Systems as your partner you can benefit from more than 15 years of experience in the development of drug delivery systems. We offer our customers reliable large-scale production processes of premium-quality products as well as manual and semi-automated clean room production of small batches to ISO class 7 (10,000) and ISO class 8 (100,000). Our know-how includes the entire inhaler product range: Powder inhalers, capsule inhalers and nebulizers. More than 50 % of the total clean room area of Gerresheimer Medical Plastic Systems are used for producing drug delivery systems – we manufacture approximately 100 million inhalers per year.

As a system supplier Gerresheimer Medical Plastic Systems takes the full responsibility and performs own order developments for drug delivery systems. We develop and produce your primary and secondary packaging according to requirement specification sheets or optimize the existing concepts or designs of the customer for injection molding. Gerresheimer Medical Plastic Systems engineers assure that all individual parts can be assembled easily and solidly and provide an optimum of functionality. Our quality guarantee: Already prior to production highest demands are applied to material selection, assembly technique and functionality of the devices.

Own pharmaceutical laboratory

We wanted to offer a significant gain of time to our customers so we set up a pharmaceutical laboratory for development-related laboratory analyses. Here, small runs are filled as samples for clinical pilot studies. The evaluation of inhalers and systems is also part of this field of activity. It goes without saying that the creation of the entire documentation later representing the basis for the authorized approval of the product (for example, the device master file) is also part of our full service concept.

From left to right:
Podhaler® capsule inhalator (Podhaler® is a registered trademark of Novartis AG).

Usage: Turbuhaler®.

Pharmaceutical

Inhalation

- Powder inhalers: Turbuhaler®, Novolizer®, Genuair®
- Nebulizer: Housing components for the Respimat® Soft Mist Inhaler
- Podhaler® device (Podhaler® is a registered trademark of Novartis AG)

Pen Systems

- Insulin pens

Autoinjectors

- Pens for emergency treatment

Injection

- Components for needle-free injection systems
- Plastic components for X-ray contrast agents
- Plastic components for injection systems
- 2-component injection systems
- Sterile wound plaster set

Transmucosal

- Various applicators

Oral

- Tablet dispenser for round, oval and squared tablet formats

From development to the point-of-sale product: Schreiner MediPharm has developed "Needle-Trap", an active label-integrated system, that helps to prevent needlestick injuries. Gerresheimer Medical Plastic Systems was tasked with developing the actual needle-protection device. The services offered by Gerresheimer Medical Plastic Systems include the development of the plastic part, including all required simulations, mold making and production in controlled area.

Image: Schreiner MediPharm

experience

»Long-term experience, a continuous will to improve and openness towards new application areas – those are the ingredients for the recipe of the success of Gerresheimer Medical Plastic Systems.«

Top quality for injection systems and tablet dispensers

Injection systems

Gerresheimer Group is one of the few companies in this segment to specialize in both major primary material categories that are essential for the pharmaceutical and life sciene industry – polymers and glass. Two experts in their respective sectors, namely Gerresheimer Medical Plastic Systems as plastics expert and Gerresheimer Bünde as specialist for pharmaceutical glass products, offer you customized solutions for injection systems.

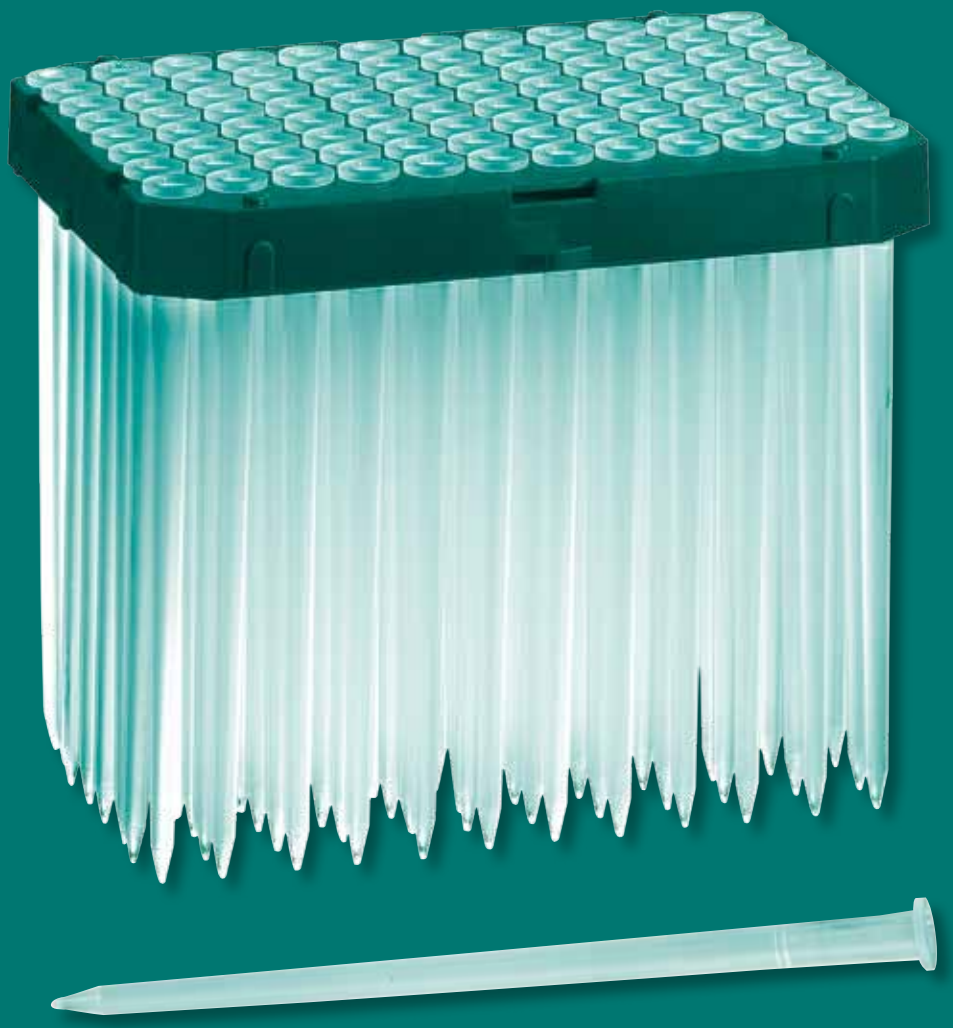
Regardless of whether conventional syringes, needle-free syringes, safety syringes, autoinjectors or pen systems are required – Gerresheimer Medical Plastic Systems is an experienced partner. In the “injection” segment, our longstanding experience in the area of „lancing devices and lancets“ represents a special advantage. We are actively involved in dermatological questions, e.g. penetration characteristics and pain development, using this knowledge for the development and production of the most sophisticated injection systems. Two-component injection systems, components for injection systems with tamper-evident closures and components for needle-free syringe systems are all current examples of how innovative products have been successfully launched.

Dispenser systems

In the field of oral care, Gerresheimer Medical Plastic Systems offers multifaceted concepts for the single dispensing of tablets, caps and effervescent tablets of all forms. The dispenser systems are always developed in close partnership with the customer and are specifically adapted to concrete product requirements.

Components for an insulin pen for diabetics.

Pipette tips



visious

»World market leaders such as Roche Diagnostics, bioMeriéux and Ortho-Clinical Diagnostics trust in the reliability and availability of our innovative solutions.«

Medical Technology

Laboratory Diagnostics

- Cuvettes
- Pipette tips
- Sample vessels
- Micro well plates
- Filter tubes
- PFA capillars
- Test cards for microbiological system
- Reagent racks
- Sterile nutrient solution carrier

Molecular Diagnostics

- Micro fluidic cartridge for nucleic acid analyses
- Disposables for diverse analysis systems
- Sample vessels for PCR analysis

Point-of-care tests (near patient testing)

- Rapid tests for Cardiac Monitoring
- Test cartridges for the quantification of hemoglobin in blood
- Test cartridges for hematology test systems
- Immunological rapid tests for whole blood
- DRUGWIPE® (lateral flow test for drugs of abuse)
- Rapid tests for microbiological purposes (e. g. food)

Diabetes Care

- Lancing device ACCU-CHEK® Mobile FastClix
- Lancing device ACCU-CHEK® Multiclix
- Lancing device ACCU-CHEK® Softclix®
- Lancet stack for ACCU-CHEK® Mobile FastClix
- Lancet stack for ACCU-CHEK® Multiclix
- Various lancets for lancing devices

Laboratory disposables from Gerresheimer Medical Plastic Systems – innovative customer solutions

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. Gerresheimer Medical Plastic Systems is your expert for customer-specific laboratory disposables.

Our main focus is on product-specific requirements: Optical quality, resistance to chemicals and wetting behavior. Consistently high quality and identical standards of reproduction are mandatory since even slightest deviations have adverse effects on optical and chemical analytical procedures and could lead to misinterpretation of the results. A reliable selection of materials as well as precise and complex molds are essential for sensitive products that require flawless quality. The enormous quantities in which they are produced also necessitate a high degree of process automation. We develop specific products and turnkey solutions. These efficient high-class production systems consisting of automated handling equipment are directly coupled to our injection molding machines, nest-specific picking systems, test systems and automated assembly and packaging lines. This way Gerresheimer Medical Plastic Systems produces cuvettes in annual quantities reaching into billions.

From left to right: Well-Cell carrier, reagent kit.

Reliable quick tests and prize-winning lancing devices

Gerresheimer Medical Plastic Systems also offers full service in the Point-of-care area. This applies to drug detection, pregnancy tests, detection of emergency parameters or allergy tests: We develop and produce your complete instant test. Here, we focus on user-friendly housing designs and an optimum connection technique such as snap fits, adhesion or heat-seals.

From material to just-in-time delivery

We select the best material to suit the required flexibility of tests, carry out cost-efficient large-scale test production processes, assemble test strips, label quick tests and ensure point-of-sale delivery of the tests. With our own test strip production adjacent to our plastics plant we can avoid long waits. The insertion of test strips into the housings is executed under special climate, temperature and air humidity conditions. Even the logistic transport by means of special-purpose vehicles is tailored to product-specific requirements.

Diabetes: Making your life a little easier

With 15 years of special expertise in diabetes care, Gerresheimer Medical Plastic Systems develops and produces lancing devices, lancet drums and lancets for painless blood testing. Our extensive expertise and knowledge of insert molding for the production of injection needles is based on many years of experience in the production of billions of lancets. Gerresheimer Medical Plastic Systems significantly improved this production process, which now allows one-step insert molding of the finest needles with a hard-soft-component and subsequent automatic loading of lancets into the drum.

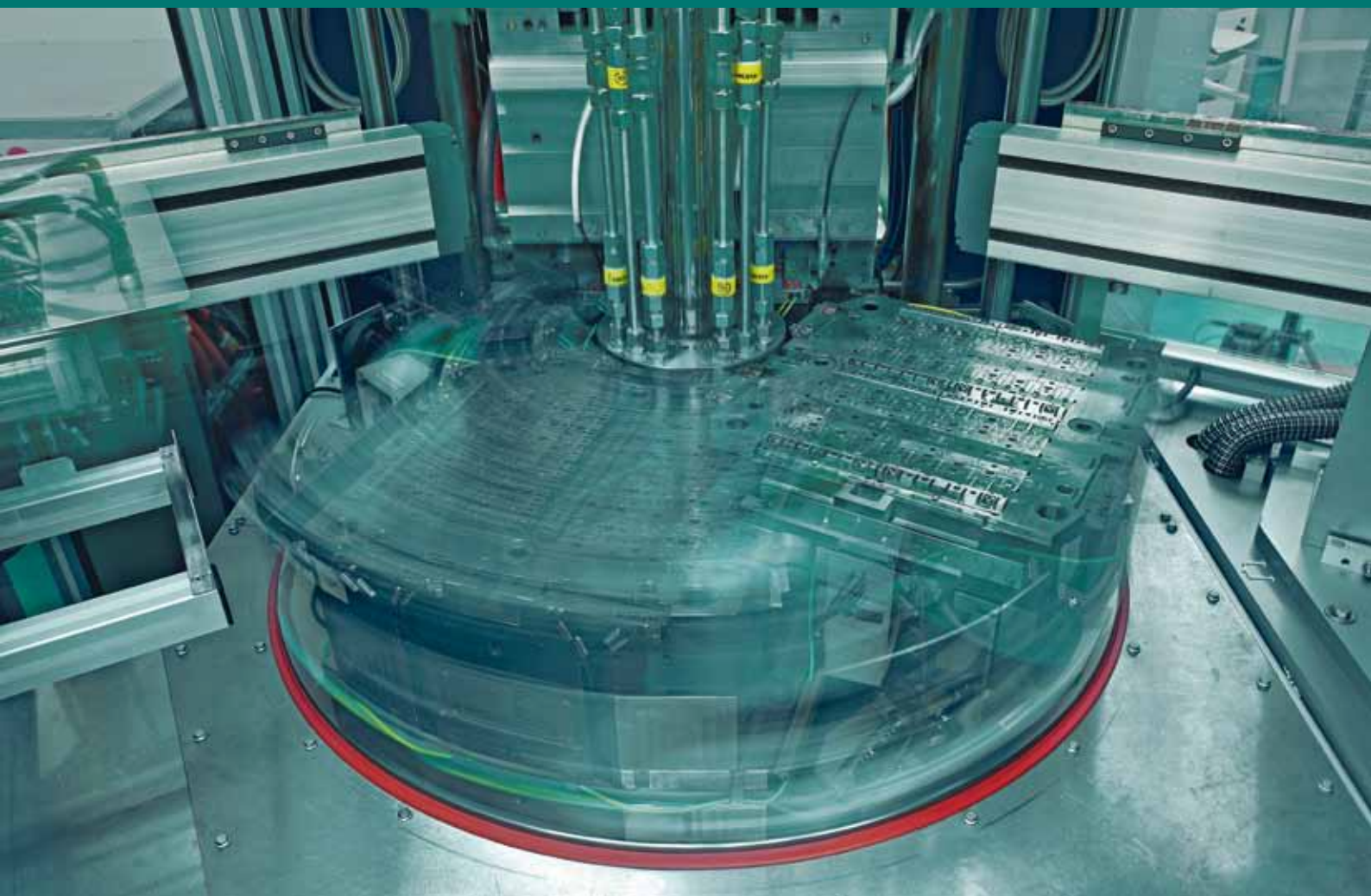
We supply the entire range of diabetes products: our portfolio is comprised of products for diabetes diagnostics as well as diabetes treatment solutions – thanks to our extensive expertise in the production of infusion sets and insulin pen systems, we know exactly what our customers need. We hope to improve the day-to-day situation of diabetes patients.

Test cartridge for a hematological screening system: Gerresheimer Medical Plastic Systems was responsible for filling the cartridge with the buffer solution that was required for the test.

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

excellence

Rotary-table machine for lancet production.

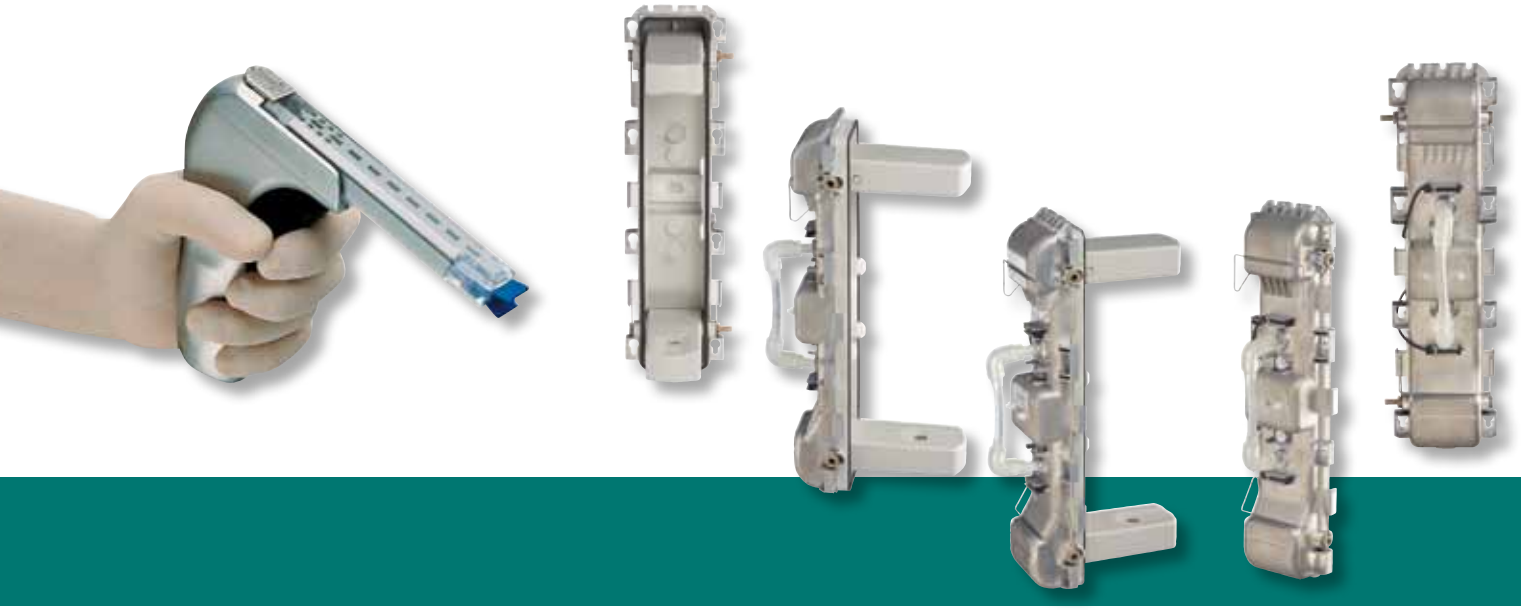


Precision and quality for Medical Technology

Worldwide, approximately one million people suffering from diabetes need regular treatment. Thanks to the enhancement of existing systems for the separation of blood and of dialysis devices, both the quality and the expectancy of life are rising continually. Correspondingly high is our responsibility for precision and quality. With the respective know-how, optimum production conditions and individual production processes, Gerresheimer Medical Plastic Systems provides the best prerequisites for high-quality products for the medical-technological market. In addition to an automated high-volume production we also produce small and medium runs. Depending on the number of pieces we decide for manual, semi-automated or fully automated production lines.

This way we achieve the individual possible maximum cost efficiency in each case. Our full service concept also applies to the Medical Technology area. Gerresheimer Medical Plastic Systems undertakes the assembly, preparation of deliveries, packaging and cares for the procurement of diverse purchased parts. For this we work with strategic partners that have to perform regular quality audits and meet those strict requirements with a quota of 100%.

Increasingly, modern devices allow measures for rehabilitation and treatment to be carried out at home by the patients themselves. This is why the segment of Home Care products has become another focal point for Gerresheimer Medical Plastic Systems. Your special advantage: We also perform the implementation and integration of the required electronics in the final device. The implementation of electronic components is already taken into account by our engineers during the development phase so that you also get everything “out of one hand”. Gerresheimer Medical Plastic Systems is your partner on all stages of the project – up to the complete assembly, printing, ready-for-sale packaging and CE-certification.



From left to right: Scalp clips, Components for dialysis machines.

Flow sensor for respirator.

Medical Technology

Surgery

- Scalp clip system
- Operation handle
- Components for blood pump

Urology

- Catheter

Dialysis & Blood Therapy

- Adsorber housing
- Bicarbonate cartridges
- Dialyzer housing
- Parts for dialysis machines

Support across the entire production 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.

Gerresheimer Medical Plastic Systems

Gerresheimer item GmbH	Technical Competence Center	Production
Product	Process / industrialization	From injection molding to the finished product
Innovation management IP Management Design Development Optimization for polymer processing Prototyping Quality management Clinical studies / sample specimen	Large-scale construction Manufacturing equipment engineering Process development Project management Quality planning Mold making Automation Engineering Production launch / Pilot run	Injection molding (clean room) Assembly (clean room) Product finishing Quality assurance Pharmaceutical filling Packaging Freight management: just-in-time

Full service: We turn visions into products ready for market

Our service portfolio

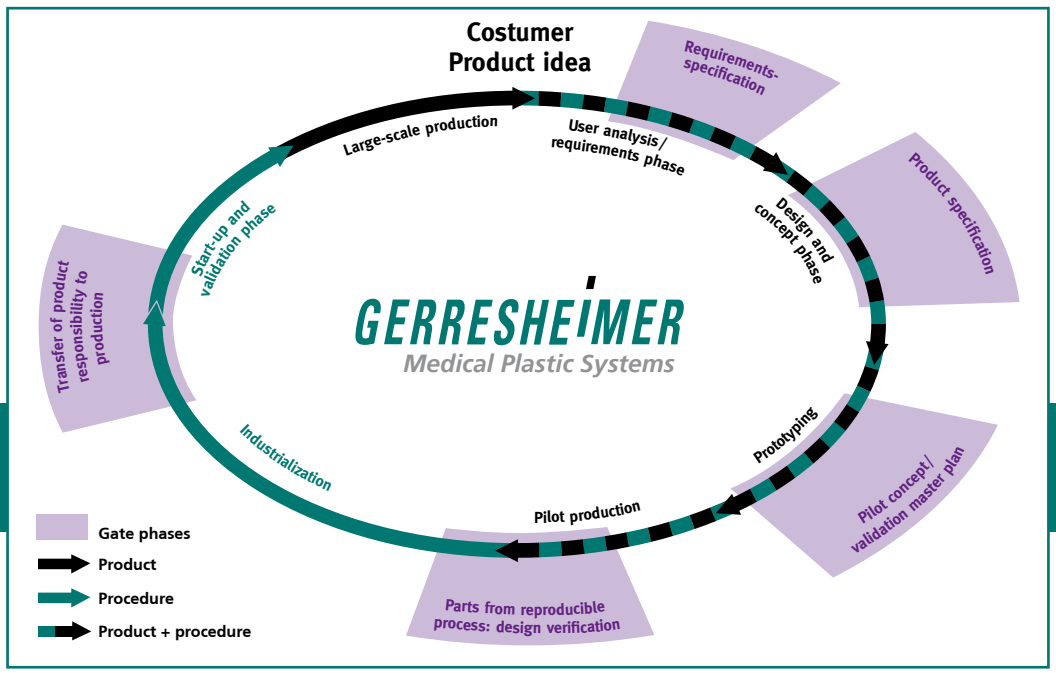
Products are born from ideas, mature solutions are the product of visions. Our service portfolio covers all stages of the development and production chain – from initial drafts, product design, concept studies and ratings with cost analysis, product, process and manufacturing equipment engineering to mold making, automation engineering, large and small batch clean room production under FDA/GMP approved conditions, manual, semi-automatic and fully automatic assembly as well as fully automatic function tests right through to product finishing, pharmaceutical filling, packaging and international distribution.

Tailor-made service package

Starting a project with Gerresheimer Medical Plastic Systems provides you with flexible options. If you wish to advance the development of a product from an existing stage, optimize an existing product or modify the configuration to suit polymer processing, our teams at the Technical Competence Centers of Wackersdorf (Germany) and Peachtree City (USA) are your experts. The TCC team consists of experienced members with special knowledge of the industrialization of your products prior to production with just-in-time delivery.

From idea to product

Gerresheimer item GmbH is your ideal partner for completely new developments, i.e. initial drafts that have matured into products. A service provider for strategic product development and design with more than ten years experience. Gerresheimer item GmbH works hand in glove with our team of engineers at the Technical Competence Centers at Wackersdorf (Germany) and Peachtree City (USA). Together, they will develop the design for manufacturing to be integrated directly into the product design stage. Your benefit: reduction of the lead times, lower costs and a minimized project risk, as optimization for polymer processing after product development is no longer necessary. After completion of the product design/product development stage at Gerresheimer item GmbH, you are free to decide on your next step. Our service portfolio is as diversified as your product range.



Understanding the end user is where development begins

At Gerresheimer item GmbH, we aim to be involved from the initial conception stage onwards. Gerresheimer item GmbH has more than ten years experience and expert intelligence in strategic product development and design of pharmaceutical and medical technology products. It was deliberately set up as an independent group member. For customers, developing products with Gerresheimer item GmbH means shorter lead times, lower costs, and a minimized project risk, as optimization of the product for polymer processing is no longer necessary.

Complete service provider

Gerresheimer item GmbH's portfolio of services extends from concept development to production-ready product. It includes consultancy and support during the intial project stages, assistance during design development, and freedom to operate, as well as engineering, prototyping, clinical study coordination and clinical sample production.

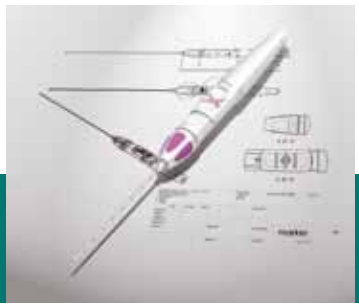
Attractive design increases the utility value

The team is comprised of twenty specialists with a different take on product design and development. The main focus is on user requirements and specifications, functional and technical demands but also on matters of design, as even buyers of medical products make decisions based on their emotional and sensory perceptions of the product quality. Hence, highly sophisticated medical devices need to combine aesthetic appearance with functional and ergonomic form.

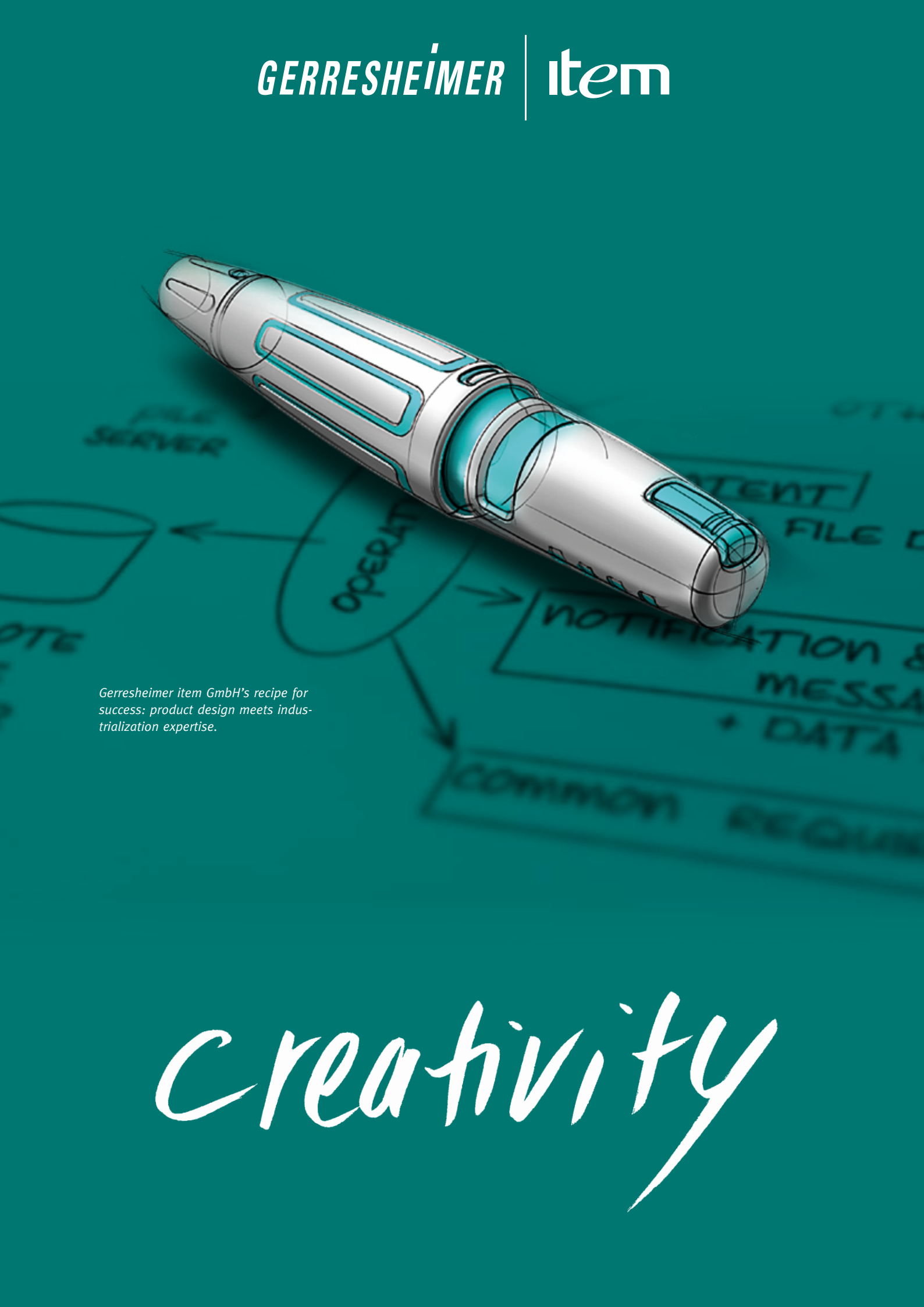
We work hand in glove with the Technical Competence Centers. The industrialization experience of many years is brought to bear on our product development processes. This way, essential requirements such as manufacturability, assembly and testing capability of the new product are taken into account as early as the conception stage. Gerresheimer item GmbH is distinguished by its market intelligence combined with design and engineering experience.

Product management:
Knowing the market and its requirements

Developing a successful product starts with a systematic analysis of the market, user requirements, the competition and the patent situation. Gerresheimer item GmbH focuses on the analysis of all product-related information, carries out user surveys and, based on the findings, develops the basic conditions for product design and development.



GERRESHEIMER | item



Gerresheimer item GmbH's recipe for success: product design meets industrialization expertise.

creativity

Product design meets industrialization expertise

Product design: More than just good looks

The findings of the product management team have an immediate impact on our product design and development with the objective of integrating market requirements and functional and technical product specifications into the project. This includes combining aesthetic appearance with functional and ergonomic form. Intuitive and simple operation is essential for products that are developed for the medical and pharmaceutical industry. The Gerresheimer item GmbH runs usability studies on several alternative design concepts. The most promising design will be optimized and used for the production of clinical sample specimens.

Product development:
Thinking ahead to production

In addition to the design, product development has to ensure that the concept is practicable in an industrial production process. The Gerresheimer item GmbH designs and develops products that are suitable for polymer processing and are suitable for mass production. Together with the customer, we will define the benchmark data for the new product. If required, we will also compile a functional and requirement specification including all production and plastics processing-related aspects.

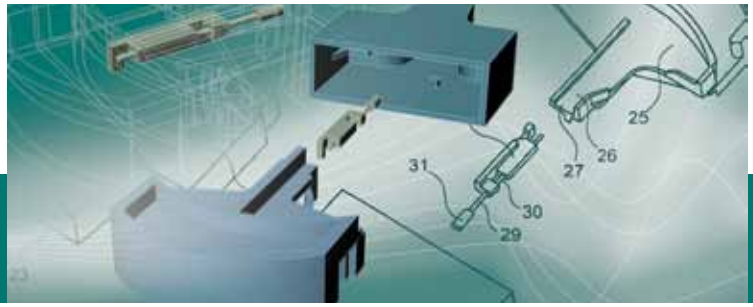
Patent management:
Legal basis and market edge

Strategic patent management is essential for the development of medical and pharmaceutical products. In addition to patent protection of all ideas that came up during product development, the Gerresheimer item GmbH uses its patent research intelligence to identify trends and to systematically use all opportunities that turn the technical and innovative competence of our customers and company into a durable market edge.

Product development means systematic and gradual risk minimization

Gerresheimer item GmbH operates a systematic five-phase product development process. This approach offers customers reliable methodological risk minimization while generating the documents required for official approval. Our phased model guarantees maximum reliability and provides the basis of our successful cooperation.

Thanks to our national and international network of suppliers and service providers, we can also help you with manufacturing management and coordinate the cooperation between OEM, developer, mold engineer and manufacturer.



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Gerresheimer item GmbH: Service portfolio

Innovation management

– Market research and user survey

IP Management

– Technology Landscape and FTO analysis

Design

– From design strategy to usability design

Development

– Laboratory-tested product functions

Design suitable for polymer processing

Series design

– CAD simulations, production and assembly specifications

Prototyping

– Rapid Prototyping, Rapid Tooling and design verification

Quality management

– Specification, risk analysis, design control

Clinical studies/sample specimen

Pilot runs

Technical Competence Center – from the product idea to series production release

Develop centrally – produce globally

The development centers (Technical Competence Center/TCC) at Wackersdorf (Germany) and Peachtree City (USA) are the "technical heart" of Gerresheimer's Medical Plastic Systems Division – both in terms of product and process development. Simultaneous Engineering at the TCC covers the entire production process right through to large-scale production. A total of 250 engineers, technicians and skilled workers from various segments work hand in hand on more than 10,000 sqm. Gerresheimer Medical Plastic Systems follows a strategy of diversification. Production takes place locally so as to provide production capacities close to our international customers. All important cross-departmental functions right through to the launch of large-scale production are deliberately pooled under the roof of the TCC.

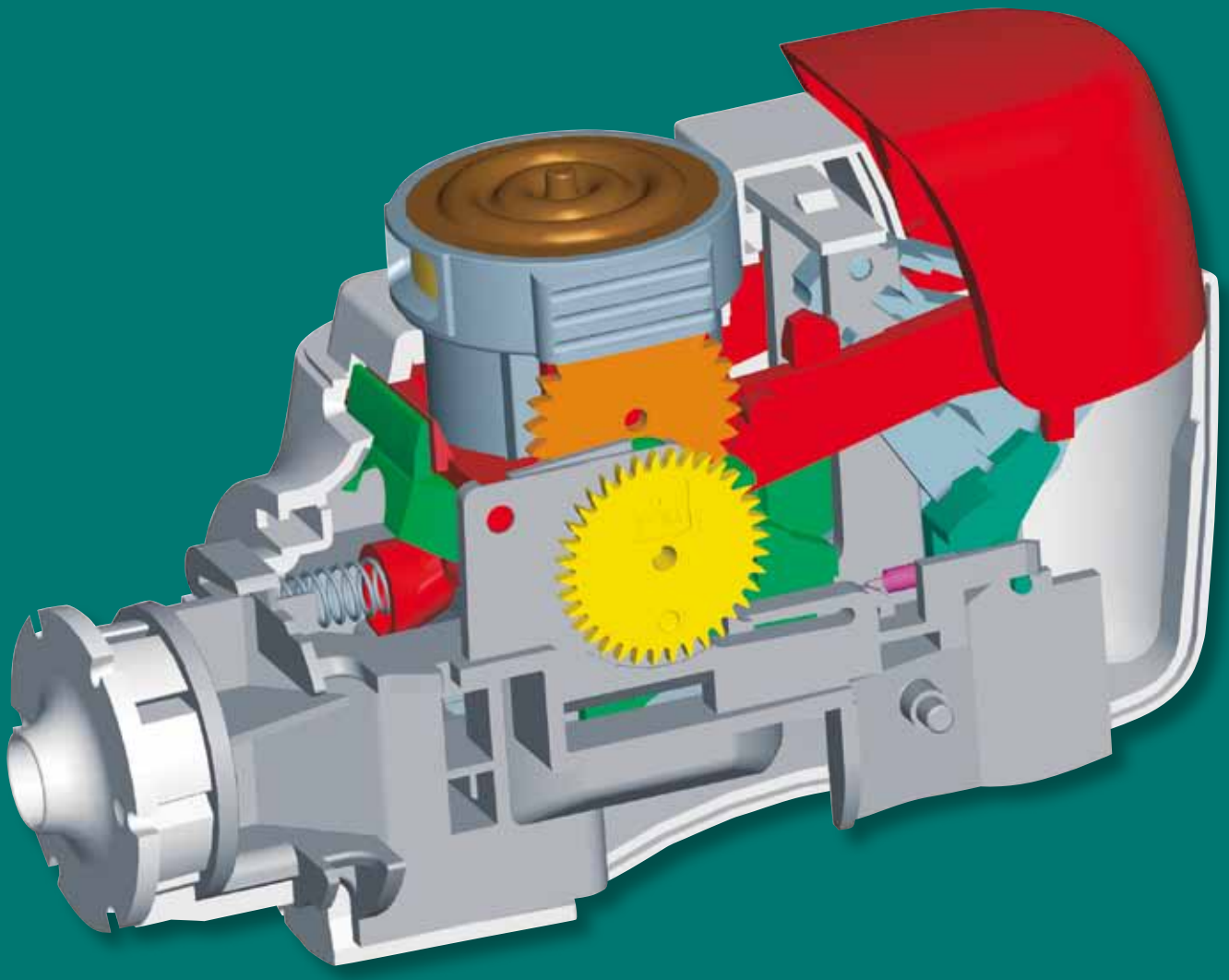
The whole world in sight

Our centralized project management schedules and initializes orders from both TCCs for different global markets, which guarantees optimum cost management for your project. Experienced project managers direct the international distribution of resources and coordinate the assignment of on-site project managers at all of Gerresheimer Medical Plastic Systems's international locations.

Knowledge and innovation network

A constant dialogue with universities, academies and well-known research facilities ensures that the TCC is always up-to-date. An example of this is our latest application in the area of materials testing. By means of the computer tomography we are now able to inspect objects completely with all interior geometric elements without destruction. One example of this diversification is the fact that we cooperate with Amberg-Weiden University of Applied Sciences in the area of materials testing. This way, we can use computer tomography for complete and non-destructive scanning of objects and all their interior geometrical elements. Other cooperation partners include the Institute for Plastics Processing, IKV, at RWTH Aachen University, the Fraunhofer Institute for Production Technology in Aachen, University of Regensburg (electrical engineering) and many more.

"Develop centrally – produce globally". Following this strategy, Gerresheimer Medical Plastic Systems has been operating a Technical Competence Center (TCC) in Wackersdorf (left), where engineers from all areas of expertise work hand in hand to develop products of outstanding quality. In 2009, Gerresheimer Medical Plastic Systems opened a separate Technical Competence Center for the US market at its Peachtree City facility (right), which has been cooperating closely with the experts at the think tank in Wackersdorf.



The Novolizer®, developed by Almirall Sofotec GmbH and produced for Almirall represents the highest level of technical competence.

Simultaneous Engineering at the TCC covers the entire production process right through to large-scale production:

- Manufacturing equipment engineering
- Process development
- Project management
- Quality planning
- Mold making
- Automation engineering
- Production launch

The think tank

Flexibility at all production levels

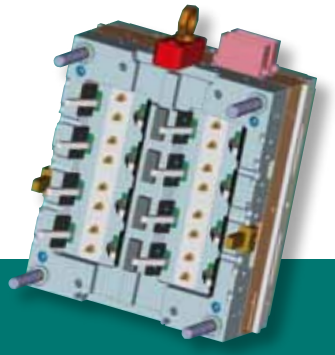
At our TCC development department, a team of fifty specially trained experts work at more than 35 state-of-the-art CAD workstations to develop product solutions that are suitable for polymer processing as well as designing and manufacturing molds and automation solutions that are tailored to customer- and part-specific requirements. Customers benefit from our flexible approach to their projects: we can pick up from an existing development stage, advance or optimize the product for polymer processing. Production- and assembly-related aspects are taken into account at the development stage. Calculation and simulation ensure the suitability of the product for polymer processing as well as post-production assembly and testability.

Computer Aided Engineering

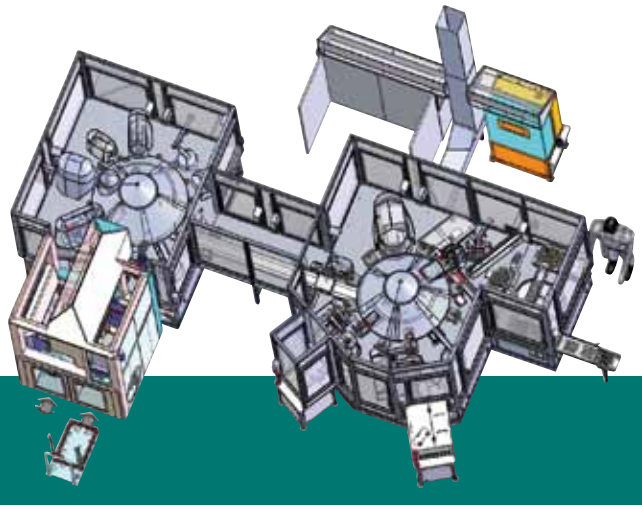
We carry out injection molding simulation programs as Moldflow so as to ensure that the finished plastic product is free from defects or material clusters, to determine the best gating points and process-stable injection parameters. FEM (finite element method) helps us identify and optimize the properties of molded parts in terms of their structural behavior – at the construction stage. Viability studies, statistical tolerance analyses, the adaptation of technologies to the customer project, prototyping and the corresponding FMEA complete our service portfolio. We design and manufacture all molds and automation solutions that may be required during the production. In cases where test results and simulations lead to construction modifications, these improvements are carried out in close cooperation with our mold and special machinery engineering department.

35 years of experience are evidence of quality

Gerresheimer Medical Plastic Systems is your industrialization partner with more than 35 years of experience in the development of medical plastic systems.



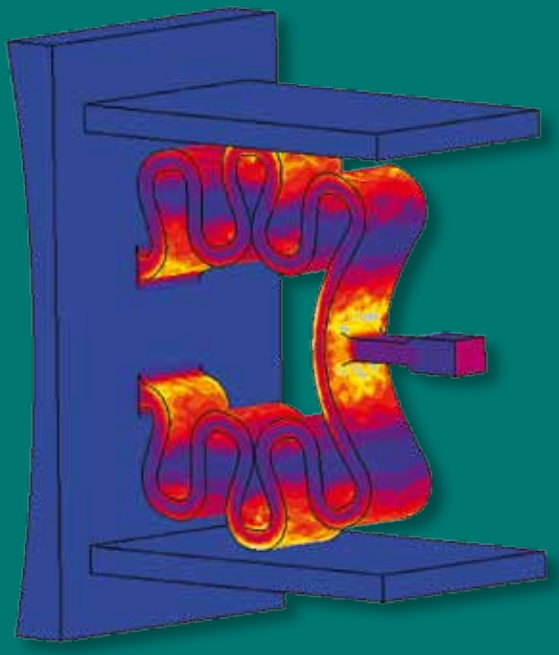
Hot-runner mold



Sophisticated plant for the preparation of primary packaging.

»Product-specific simulations ensure a product's feasibility with a focus on polymer-specific properties, its potential for highly automated assembly and its auditability. Our customer solutions are subjected to feasibility studies prior to production.«

Moldflow analysis



Finite element analysis

Computer Aided Engineering

- 3D Design
- Moldflow
- Finite element analysis
- Computer tomography
- Statistical tolerance analysis
- Multi-body simulation
- Numerical fluid mechanics (CFD: Computational fluid dynamics)

We construct the tools for your success

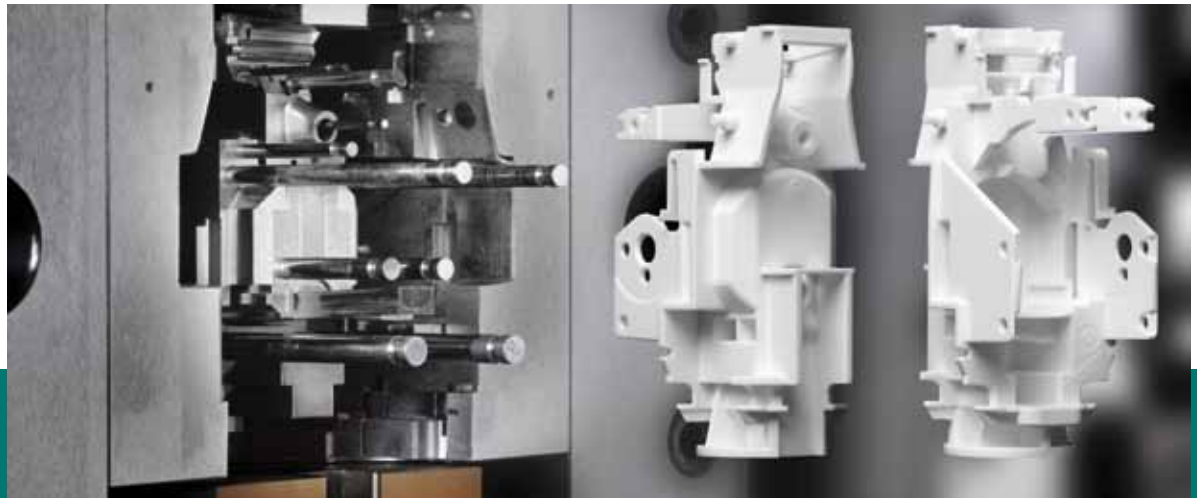
Gerresheimer's Medical Plastic Systems mold making department has a long tradition. As early as 1958, Gerresheimer Werkzeugbau Wackersdorf GmbH started manufacturing sophisticated injection molds, mainly for clean room production.

Quality assurance without cutting corners

The department operates state-of-the-art spark and wire eroding machines, high-precision grinders for all processes and micro HSC milling machines. Strict quality assurance is top priority during the entire production process, as high-precision molds and tools are the cornerstone of excellent product quality. Hence, the in-house standards laboratory of Gerresheimer Werkzeugbau Wackersdorf GmbH operates only state-of-the-art measuring equipment such as CNC image processing machines. More than sixty specially trained experts manufacture low- and high-cavity molds (up to 144 cavities) with micrometer precision, single and multi-component molds, indexing plate molds, hot-runner molds, insert molds (encapsulation of needles and lancets) as well as stack molds. We manufacture molds for internal as well as external production.

Award-winning mold making department

Top marks at the renowned "Excellence in Production" competition conducted by RWTH Aachen University and Fraunhofer Institute for Production Technology, where Gerresheimer's Medical Plastic Systems mold making department was voted number one in the category "Integrated Mold Maker With Less than 100 Staff Members" in 2009 and 2011, attest to the specialist's premium quality in mold making. The following criteria were relevant for our success: a high degree of customer satisfaction, early customer involvement and an outstanding adherence to deadlines. Gerresheimer Werkzeugbau Wackersdorf GmbH is affiliated with the Technical Competence Center. The uninterrupted flow of construction data directly from the TCC to all machines and even to workbenches ensures that our production equipment always operates to the most current draft status.



The manufactured molds are distinguished by their complex geometries and impressively narrow tolerances.

8-cavity hot-runner mold – Excellent products call for excellent molds. The in-house mold making department of Gerresheimer Medical Plastic Systems has a long tradition.

Mold Technologies

- High-cavity injection molds
- Multi-component molds
- Hot-runner injection molds
- Rotary table molds
- Stack molds
- Indexing plate mold
- Insert molding (encapsulation of needles and lancets)

We construct the tools for your success

The best solutions for exacting requirements

Developing and manufacturing downstream equipment for our molds, we offer customers product-specific, high-performance complete systems for highly automated polymer processing. We develop manufacturing concepts and complex lines for the production of component structures with smooth production processes. Our team of automation systems engineers manufacture customer- and part-specific assembly, testing, handling and packaging lines, rotary table machines, linear systems as well as customized lines for pharmaceutical assembly. Being an international manufacturer, we also monitor and assist the start-up of our production equipment on the customer's site. All production systems installed by our department operate to GAMP (Good Automated Manufacturing Practice), FDA and 21 CFR Part 11.

Pilot Plant at the TCC

The TCC Pilot Plant is our practical competence center for all injection molding processes. At the Pilot Plant, 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 prototype technical-release procedure as well as mold optimization processes are the basis for the entire components verification. Important stages during this process are the setup of stable parameter settings for injection molding and the complete component measurement – documented in a complete first sample test report. Machine and process feasibility confirmations as well as mold testing for distinct periods of time (4 or 24 hour runs) complete the phase in our Pilot Plant station and directly lead to industrialization at the production site.

The Pilot Plant operates a special 200 sqm clean room to ISO class 8 (100,000) as well as a measuring chamber with product-specific testing equipment. In the measuring chamber, we operate state-of-the-art measuring units such as infrared spectrometers, thin section microscopy and three-dimensional measuring systems. We carry out force measuring and tensile tests to measure fracture strength. Development-related analyses are conducted in a polymer analysis laboratory.

At the Pilot Plant of the TCC in Wackersdorf, Germany, an inhaler component is subjected to a highly automated electro-optical test of adherence to dimensional specifications as part of an initial sample inspection report.

Highly complex linked production unit consisting of four round tact production cells: Nine single parts are brought in to become one complex assembly in this development of Gerresheimer Werkzeugbau Wackersdorf GmbH.

Automation Engineering

customer & part specific

- Assembly facilities
- Rotary table systems
- Linear systems
- Robots to insert and withdraw parts
- Testing machines
- Packaging facilities
- Lines for pharmaceutical assembly

Inhaler assembly at our production site in Dongguan City, China.

Solutions

Injection molding technologies

- 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 (IMD)
- Thin-wall injection molding
- Micro injection molding

Product Finishing

- Laser marking
- Printing
- Joining techniques

Ultrasonic and vibration welding

Laser welding

Thermoforming

Cold calking

Adhesive bonding

- Metalizing
- Lacquering

Assembly and Packaging

- Assembly of components

Fully automated

Semi-automated

Manually

- Making-up deliveries
- Sterile packaging
- Blister packaging

From injection molding to ready-to-market products

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. Before the production starts, the line set-up is simulated in order to determine the most efficient order of the individual production steps – a fast track for your product.

Full Service for full customer satisfaction

Gerresheimer's Medical Plastic Systems' Full Service strategy involves a lot more than 100 % quality injection molding. It includes many different post-production processing methods – from completion and assembly of the structural components to optical, tactile and functional finishing right through to filling, sealing and packaging of point-of-sale systems. We even take care of the procurement of high-quality external parts.

Naturally, we also carry out the surface decoration of all components. We finish post-production parts by means of printing, laser labeling, metalizing, coating and sleeving. Large-scale product finishing is subjected to the same quality requirements applied to the production of individual component assemblies: we integrate camera systems into the decoration line to ensure the immaculate quality and precise positioning of print images and labels.

We select modern, fully-automatic or lower priced semi-manual or manual assembly of complex systems to suit specific product requirements. We offer the best cost framework for each product to our customers.

Gerresheimer Medical Plastic Systems provides all services from one single source – including optimum packaging solutions that meet all requirements in terms of product protection, storage and transport. We operate fully automatic packaging lines that can be adapted to suit the specific product, if required.

Fully automated packaging lines

Challenge our team with your individual packaging specification. We meet every customer product packaging requirement. We operate fully automated packaging lines, and carry out a product-specific configuration if required.

Housing components for the Respimat® Soft Mist Inhaler.

Pharmaceutical packaging and filling

Pharmaceutical packaging and filling area

In order to meet customer requirements for a complete solution that includes injection molding, assembly, packaging and post-production finishing as well as filling the products with the active ingredient, we installed a pharmaceutical packaging and filling area. The area can be flexibly divided into units. It is comprised of three classified and certified clean rooms according to GMP class D (ISO 8) of between 70 and 90 sqm. Manufacturing different products requires physical separation of the individual production areas. In order to meet this requirement, the packaging and filling area is comprised of modular production units, which are separated by means of pressure cascades. The areas are equipped with assembly, filling and testing equipment according to the German Drug Law. Regular inspections are carried out by the District Government of Upper Bavaria to ensure compliance with quality standards. The pharmaceutical filling process is monitored by a "qualified person", a chemist with 25 years of experience in manufacturing pharmaceutical products.

Gerresheimer Medical Plastic Systems has more than ten years experience in filling and packaging active ingredients in different application systems. In 2001 we filled clinical sample specimens and stability batches of a dry powder inhaler. In this case, the filling license was limited to handling clinical sample specimens and the production of powder blends as well as filling, packaging and labeling of dispensers containing powder blends. In 2007 this filling license for clinical sample specimens was expanded to filling and packaging of application systems with implants. In 2011 Gerresheimer MPS was granted a manufacturing license according to AMG (German Drug Law), which allows Gerresheimer Regensburg GmbH to package and assemble these products according to AMG at its Pfreimd facility. We load pens for emergency treatment of allergic reactions with epinephrine carpules supplied by the customer.

The pharmaceutical packaging and filling area can be flexibly devided into units. It is comprised of three classified and certified clean rooms according to GMP class D (ISO 8) of between 70 and 90 sqm.

Loading emergency pens with epinephrine carpules supplied by the customer.

worldwide

– Pfreimd | Germany

– Küssnacht | Switzerland

– Indaiatuba | Brazil

International production sites

– Peachtree City | USA

– Dongguan City | China

– Horšovský Týn | Czech Republic

Gerresheimer Medical Plastic Systems is as international as their customers

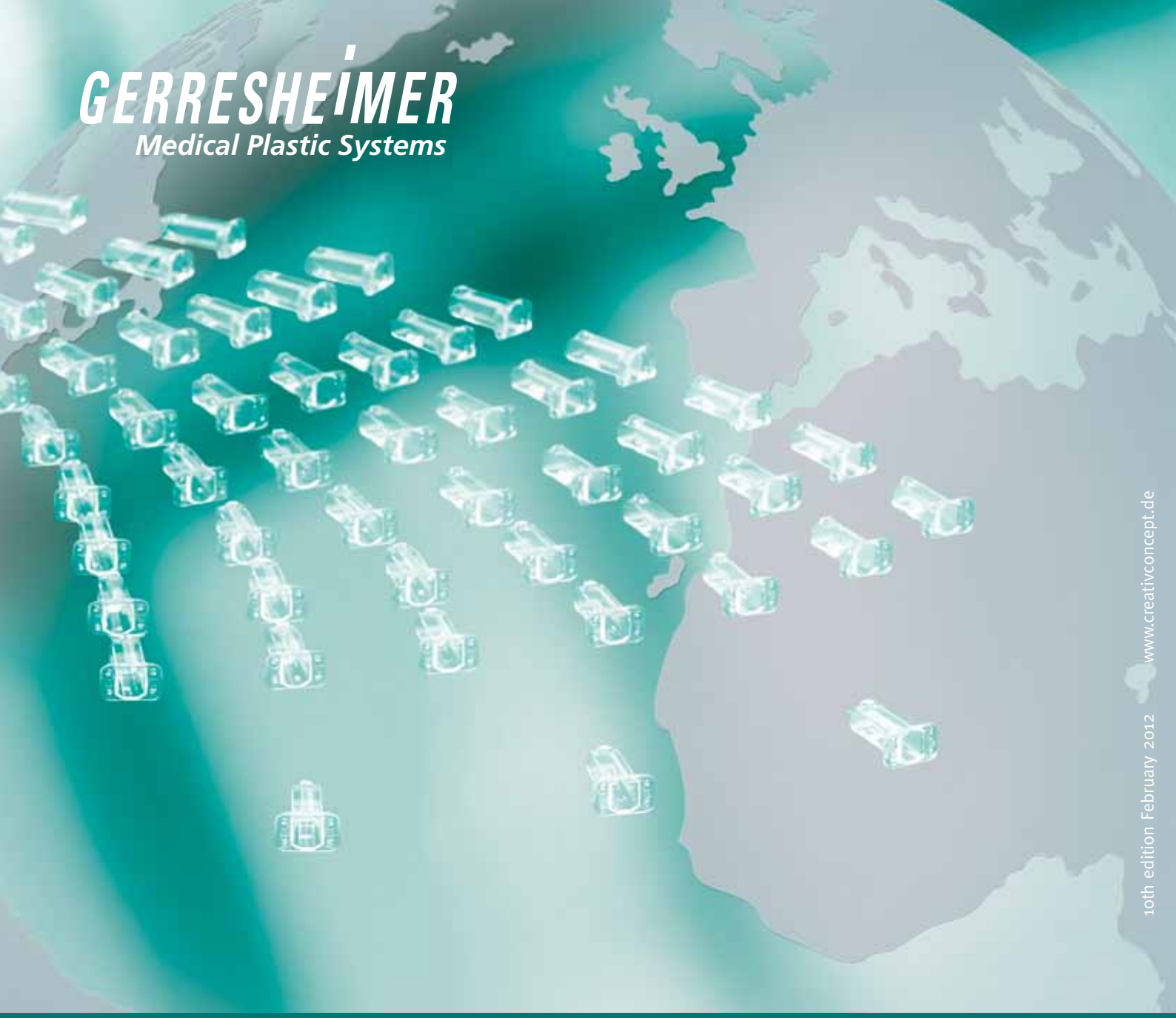
As a global player we think and act international. Therefore, we operate production sites with a total of almost 35,000 sqm to about 300 injection molding machines to our customers in Germany, Switzerland, Czech Republic, the US, Brazil and China. Be it fully-automatic large-scale production, semi-manual or fully manual small batch production of complex and technically challenging products – we provide the best possible production solutions to customers all over the world.

The production of plastic medical products requires an adequate production environment. Therefore, Gerresheimer Medical Plastic Systems operates 18,000 sqm of clean room to ISO class 7 and 8 and about 11,000 sqm of controlled areas to ISO class 9. With more than thirty years of experience in clean room production and management of the entire production chain from injection molding, assembly and testing right through to clean room packaging, we are experts in the production of medical plastic systems.

High transparency and optimized processes

Today top production performances are only possible with extremely powerful data processing. For this reason Gerresheimer Medical Plastic Systems controls and monitors its complete production by means of a Management Execution System (MES). With this utility our production processes become more efficient, costs decrease and production speed rises. Finally automated quality checks linked to the production process and the well documented traceability (Backtracking capability for individual structural components or production lots) ensure that all products comply with the required quality standards.

Clean room production to ISO class 9 at our production site in Horšovský Týn (Czech Republic).



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