FLEIMA-PLASTIC

Your project partner for the development
of plastic components and assemblies

A VALUABLE PART OF THE
MASTERFLEX GROUP

Expertise in medical technology

We have been developing and manufacturing top-quality medical products made of plastic for many decades now. Under the umbrella of the Masterflex Group, together with our sister company NOVOPLAST Schlauchtechnik based in Halberstadt, we are the experts in the area of medical technology.

As a result of the affiliation within the Masterflex Group and the close cooperation among the individual specialist teams, we have a broad range of expertise in the areas of material selection, tooling and manufacturing processes for injection-molded parts and high-performance medical tubing and hoses.

We accompany our customers in implementing of the entire development process – from the idea to the finished medical technology product. We are backed by almost 50 years of experience in the production of injection molds and injection-molded parts.

As versatile a material as plastic is – our product developments made of this material can be just as diverse and individual. No matter whether you come to us with an idea, a sketch or a specification sheet, we are happy to accommodate your requirements and wishes and begin developing a solution with complete commitment.

We actively accompany our customers at every stage of the project with our experienced project team. As a reliable development partner, we support our customers in the processes of development, manufacturing, testing and approval. Moreover, we offer the option of integrating injection-molded parts in a product or in a complete assembly.

FLEIMA-PLASTIC

The FLEIMA-PLASTIC brand from Wald-Michelbach/Odenwald stands for high-quality injection-molding technology. In addition to parts for standard applications in the areas of medical technology, pharmaceutical technology, laboratory technology, cosmetic technology and food technology, sophisticated and individualized assemblies are produced. The company's own mold and tool shop guarantees highly flexible development and production in the case of complex projects – especially with regard to the target markets in question.

NOVOPLAST SCHLAUCHTECHNIK

The brand NOVOPLAST Schlauchtechnik, based in Halberstadt, offers tubing, hoses, profiles and 2D/3D preformed tubing and hoses made of practically any kind of thermoplastic. NOVOPLAST is particularly skilled in industrial and medical technology applications. High-quality medical technology products are produced in clean rooms belonging to ISO Classes 6 and 8 which are set up especially for this purpose. This makes it possible to offer customers an extremely wide range of solutions at all times.

Development and manufacturing processes

No matter which stage of project development you currently find yourself in – we can come on board with support at any milestone or time you require our expertise. In medical technology, the design of products is often very complex and individual, making high levels of consulting expertise necessary.

1 DEVELOPMENT
Concept development, feasibility study and assessment, early-stage integration of risk management

2 COMPONENT DESIGN
Plastic-appropriate and production-appropriate design, interface consideration, material definition

3 SIMULATION
Assessment of the filling behavior, flow behavior and warpage behavior, rigidity consideration, derivation of design adaptations

4 TOOL DESIGN
Development of tool concepts, design of complex injection-molding tools, integration of external solutions and technologies

5 TOOLMAKING
High levels of flexibility as a result of the company's own tool shop, state-of-the-art equipment and processing centers, precise and prompt completion of tool projects, modifications and repairs

6 PROTOTYPING
Short time-to-market realization as a result of the use of flexible master mold concepts, manually placed core inserts for near-series preproduction parts, 3D printed parts, SLS, FLM, prototypes made of production-quality materials

7 PRODUCTION CONCEPTS
Suitable solutions involving micro injection molding, insert molding and two-component injection molding. Tubing and hose/injection-molded part combinations and hybrid solutions, establishing joining processes, creating manufacturing instructions and testing steps

8 VALIDATIONS
Adoption of article-specific process validations, joining process validations, assessment of bioburden and particle loads, early recognition of critical product criteria

9 MEASURING SERVICES
Optical component measurements, determination of Shore hardness and tensile tests. In addition to this, qualitative evaluation and classification of plastic components

Ideas – the key to innovative solutions

We are more than “just” a vendor for our customers. We are a technology partner, solution finder and development partner. We accompany you through all stages of your project.

We develop a product that is perfectly aligned to suit you on the basis of your ideas and requirements. Our team of experts is at your side at every development step.

As a result of our specialization in medical technology and pharmaceutical products, our employees know the particular requirements and master the holistic spectrum of services for successful product development.

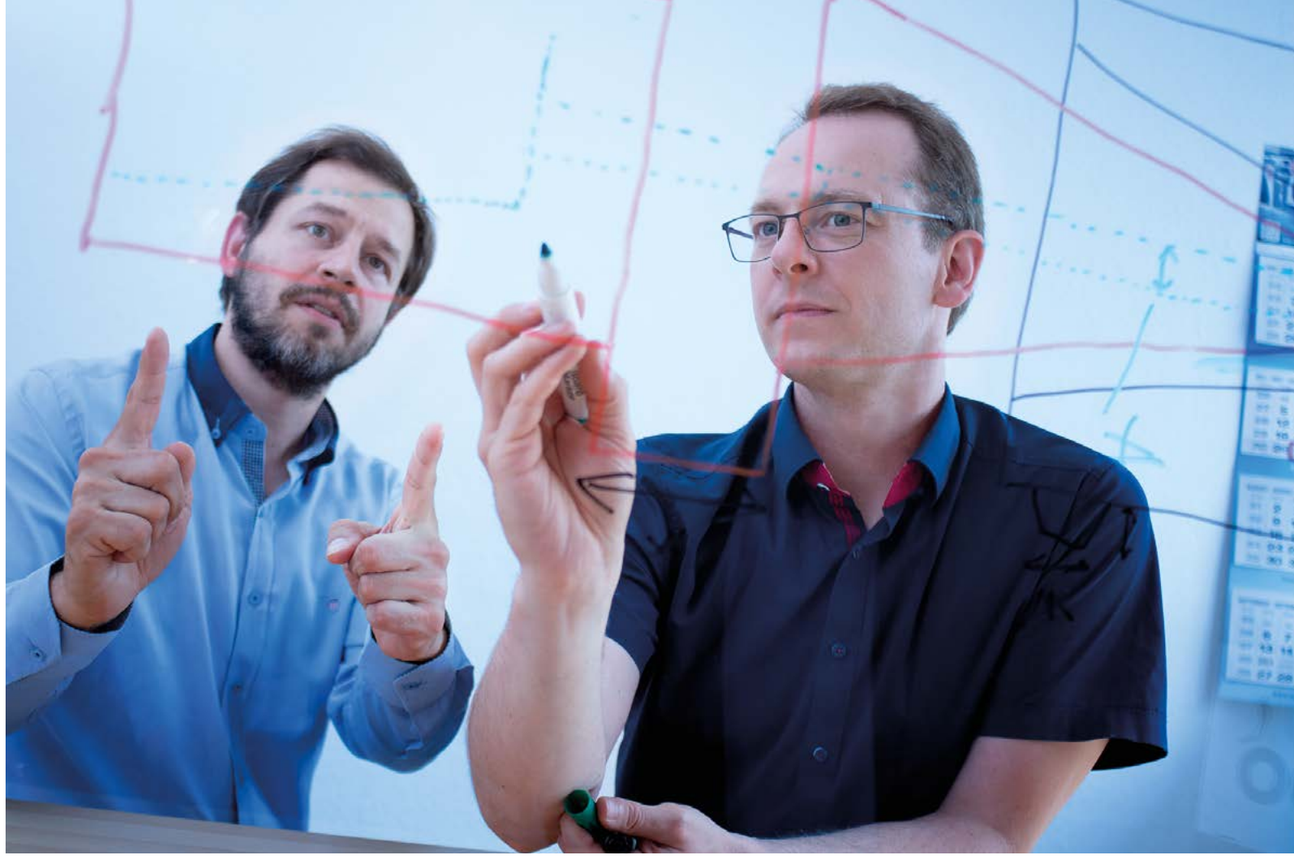
Together with you, we analyze the individual application case and the framework conditions of the task in question. For this, we consider the technologies available on-site as well as alternative implementation options. The result of this initial consideration is an assessment of the producibility and recommended adjustments. Risk considerations are integrated in this early step.

Our experiences made in an extremely wide range of application areas benefit you in developing your product idea.

During product planning, we never lose sight of our objectives, e.g. top quality, economy and innovation. Process and material know-how flows into every development project in order to create innovative and safe products on the basis of the corresponding market, customer and user needs.

Our services at a glance:

- Concept development
- Product design
- Product development
- FEM calculations
- Risk assessment
- Consulting by specialists

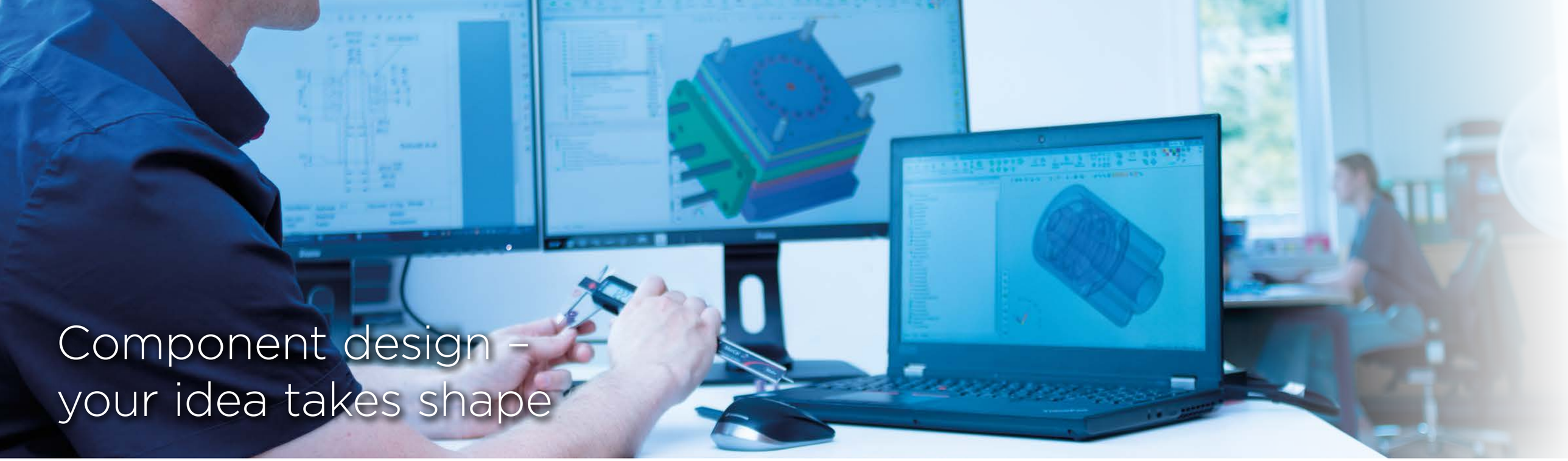


> In medical technology, the design of products is often very complex and individual, making high levels of consulting expertise necessary. For us, our service doesn't stop with the finished assembly – instead, we see ourselves as a partner to our customers, whom we also support with downstream processes such as validation, assembly or refinement
>
> *Hermann Kreyenschulte, Head of Development Injection Molding FLEIMA-PLASTIC*

Our experts from FLEIMA-PLASTIC and NOVOPLAST Schlauchtechnik provide you with ongoing customer-oriented, quality-conscious and cost-oriented support in your projects. These are characteristics that make us a competent partner – from the idea all the way to the product ready for use. Renowned partners in the medical technology, pharmaceuticals and food industries have been placing their trust in our performance capabilities for many years.

We support you:

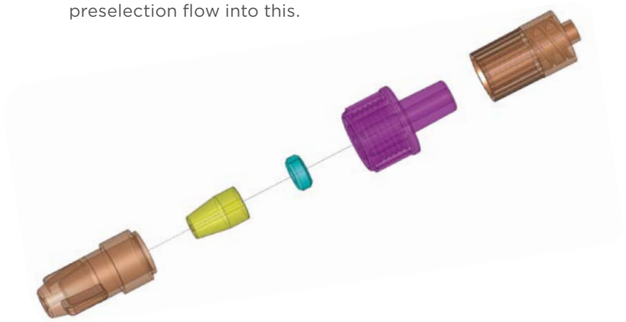
- With forward-looking concept creation
- With continuous consulting using expert feedback
- With integration of risk management at an early stage



Component design – your idea takes shape

Based on your list of requirements, the constructive design of the component is made, accounting for interfaces and envisioned joining processes.

Likewise, evaluation of wall thicknesses and material preselection flow into this.



In this stage, it is possible to make simplifications by means of component adaptations and by planning modern tool technologies, which may result in considerable savings potentials.

Plastic and production-appropriate design:
Process and material know-how flows into every development project in order to create innovative and safe products on the basis of the corresponding market, customer and user needs. For this, we use state-of-the-art methods, CA-X programs and cross-divisional project management.

Interface consideration:
Within the scope of constructive molding, component calculations and interface considerations are carried out with the support of FMEA analyses.

Material definition:
We support you in the selection of materials to suit your project. You can choose from an extremely wide range of plastics which are approved for medical applications according to ISO 10993 as well as materials which are resistant to cleaning agents and disinfectants, and all types of sterilization.

Simulation – to ensure that the basis itself is correct

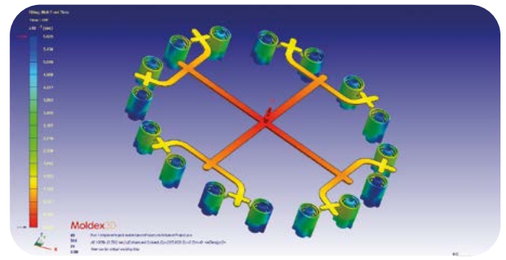
The early-stage simulation is an important point in the product development process. With the help of flow simulations during the component and tool construction stage, it is possible to make fast and precise predictions regarding flow behavior and temperature conditions in the tool. Similarly, it is possible to make predictions regarding the warpage behavior of the part geometries dependent on the plastic used.

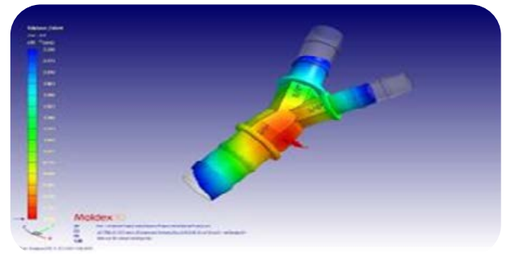
In this way, assumptions can be verified and potential problems identified. These insights flow into the subsequent tool design. Critical areas can thus by detected at an early stage, errors can be avoided, time can be saved and costs can be reduced.

The entire development process is consequently accelerated and, as a result of early-stage tool adaptations, it is possible to avoid cost-intensive tool reworking.

We offer:

- Assessment of the filling/flow and warpage behavior by means of mold flow analysis
- Rigidity consideration
- Rheological calculations and simulations
- Derivation of constructive adaptations



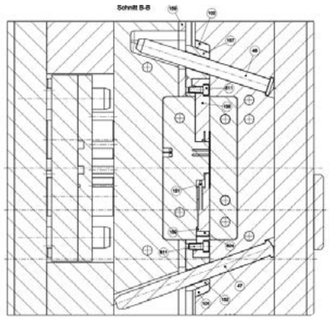


Tool design – arriving at your product one step at a time

The tool is designed by our experienced moldmakers, accounting for technical and economic framework conditions. During this step, ideas culminating from almost 50 years of injection mold design and construction and comprehensive industry-specific expertise are contributed.

Our services at a glance:

- Development of tool concepts for injection-molding and extrusion tools
- Integration of external solutions and technologies



2D drawing of an injection-molding tool

> **Sturdy designed injection-molding tools are the basis for proper article manufacturing. We allow our ideas and experiences to flow into the tool design, which makes intelligent solutions possible. The dialog necessary for this between us and our customers sets our way of working apart, which in turn leads to successful collaborations extending over many years.**
>
> *Joachim Wrba, Development Injection Molding FLEIMA-PLASTIC*

Toolmaking – where precision is called for

In our in-house mold and tool shop, it is possible to create the designed tools and molds quickly and efficiently, and make initial injection-molded samples available within an extremely short time.

Your ideas are turned into reality using state-of-the-art manufacturing techniques. On the basis of the component design and the results of the simulation steps, the injection-molding tool is built according to the specified tool design. Based on our internal manufacturing guideline, we can guarantee a long tool life and absolute tool precision. All the necessary individual toolmaking steps can be represented in-house.

In our mold shop, experienced specialists are at work who are continuously advancing their training. In addition, we offer all the services of a modern toolmaker, e.g. tool repairs, wire-cut and die-sink EDM, creating graphite electrodes, HSC milling, laser welding, jigmaking, etc. Besides the production of technical products, the tool shop is certified according to ISO standards.

Moreover, as a result of the flexible structure of our in-house tool shop, we are able to make product changes at short notice as well as carry out tool transfers, in part with any necessary adaptation work.

Fast response times

We produce your desired tool for you in top quality. Thanks to state-of-the-art equipment, competent staff and flat hierarchies, all of our development steps are designed for efficiency.

Prototyping – thorough testing is half the battle

Before series production starts, product development should first be put through its paces.

There are many unknowns on the path from the idea to the finished product. Prototypes help to avoid possible pitfalls between the initial theory and practical implementation. Therefore, innovative approaches are necessary for rapid product deployment. In this way, with our flexible master molds and the production of contouring mold inserts, we can produce prototypes within a brief time period, enabling short time-to-market steps.

The prototypes are built using materials in production-level quality, making it possible to run realistic functional and conformity tests or produce 3D-printed dummies. All services are individually produced according to medical standards.

By using additive processes, it is also possible to provide printed components. The corresponding process is nominated and undertaken, dependent on the requirements of the components.

Production concepts – our strength lies in diversity

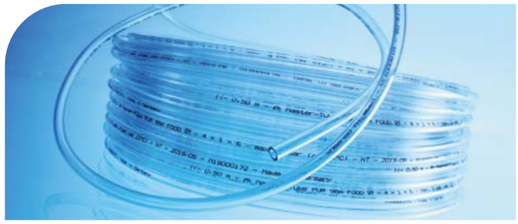
The Masterflex Group unites all technological equipment and injection-molding and extrusion know-how for the production of modern plastic products under a single roof.

Extrusion

There's just no substituting extruded plastic tubing/hoses and profiles in medical technology. As a result of individual, application-based development and implementation of these products, we can define solutions for practically any application area. With the help of the extrusion lines installed in our clean rooms, we are able to cover a diameter range of 0.50 – 20.00 mm, achieve manufacturing speeds of more than 200 m/min and facilitate the processing of a very wide spectrum of materials.

Producible product groups:

- Monolayer tubing
- Multilayer tubing
- Multilumen tubing
- Twin tubing
- Hybrid tubing
- Reinforced tubing
- Laser-marked tubing
- Individual solutions



Injection molding

Precision is one of the highest-priority requirements for plastic parts in medical technology. Our injection-molding production at FLEIMA-PLASTIC takes place under controlled processing conditions. We have more than 23 injection-molding machines, our own fully equipped tool shop and automatic assembly machines. In addition, we provide extensive know-how in various joining and adhesive technologies, including ultrasonic welding and UV bonding.

Furthermore, tubing and hose/injection-molded part combinations and hybrid solutions are also possible. We have established joining processes for this, e.g. 2-component bonding, solvent welding, CA and UV bonding and ultrasonic welding. As a result of adopting and coordinating all component design services, e.g. interface consideration, procurement analysis of purchased parts and nomination of joining methods, consistently lean implementation of complex projects is made possible.

We offer:

- 23 injection-molding machines with clamping pressures of 150 kN to 3,500 kN
- The latest manufacturing technologies
- Digitalized production for the greatest transparency
- Single- and multiple-component injection molding
- Insert technology
- Hybrid solutions
- Laser marking
- Ultrasonic welding
- Qualified ISO Class 7 clean rooms
- Class 6 to 8 clean rooms as per DIN EN ISO 14644-1
- Batch tracing
- Vertical injection molding

Validation – better safe than sorry

The production of injection-molding tools for medical products is characterized by strict quality

requirements. Consequently, after the production and qualification of tools, validation is a necessary prerequisite for manufacturing products that are of the corresponding quality at all times, thus making the road to product approval smoother.

As a result of the risk management process integrated in product development, it is possible to identify critical product criteria at an early stage. These are analyzed and evaluated by means of appropriate product and process validations. Safe products and assemblies as well as reduced expenditures for audits during production are the objective here. Similarly, it is possible to carry out injection-molding validations as well as evaluate particulate and microbial loads.

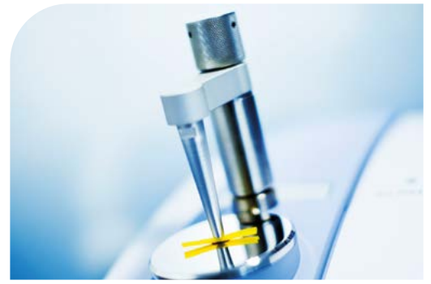
Measuring services – accuracy you can rely on

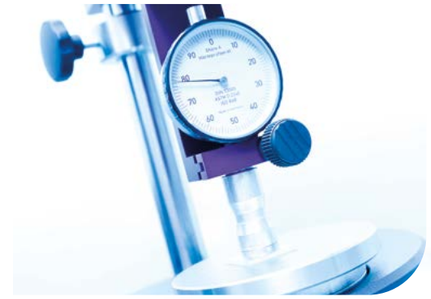
FLEIMA-PLASTIC and NOVOPLAST Schlauchtechnik have installed a comprehensive measuring technology portfolio for assessing and analyzing product properties. In addition to traditional disciplines, e.g. determining Shore hardness or optical component measuring and tensile testing, it is possible to make a qualitative evaluation and classification of plastic components by means of FTIR (Fourier transform infrared spectrometer).

Our equipment enables precise assessment as well as verification of material properties for reverse engineering. This involves reversing the development and/or production process, e.g. from the product all the way to the design drawing; application areas for reverse engineering include product development, quality testing and troubleshooting.

We offer:

- In-house measuring and testing methods
- Measuring microscopes
- Tensile and pressure test equipment
- Gear metrology
- Material tests with DSC (differential scanning calorimetry)
- Moisture content measurements
- Surface roughness measurements





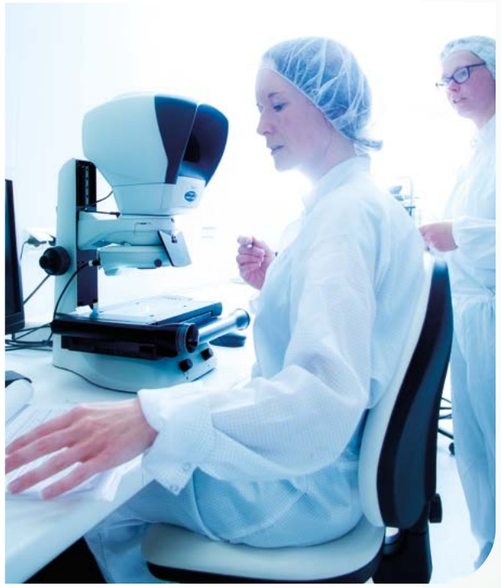
Quality management – your satisfaction is our benchmark

Products in the areas of medical technology, diagnostics and pharmaceuticals are subject to especially strict requirements.

We always do our best to produce qualitatively high-value and safe products that you can rely on in every respect.

We guarantee this quality promise with our certified quality management system (QMS) in compliance with DIN EN ISO 9001 and DIN EN ISO 13485. In order to improve the efficiency and effectiveness of our QMS on an ongoing basis, we regularly collect and evaluate key figures and draw our conclusions.

With a holistic mindset and a continuous drive for quality, we turn ideas into reality using state-of-the-art technology – especially for products for which the utmost precision is essential. International customers from the areas of medical technology, cosmetics and the food industry already trust in our expertise.



Clean room

The complex and widely varied application areas of medical products demand technical know-how as well as solid experience in this area. This includes production under “clean conditions” – production in the clean room.

At our production sites in Halberstadt and Wald-Michelbach, we have Class 6 to 8 clean rooms (as per ISO 14644-1).

In addition to the actual production in the clean room, our quality promise includes permanent monitoring of clean room conditions and the corresponding training of our staff. Moreover, internal audits are also conducted.

We offer:

- Management system as per ISO 9001, ISO 13485 and ISO 14001
- Digital solution for quality management and quality assurance
- Qualification of tools, plants and equipment
- Validation of manufacturing processes

Technical support – we don’t leave on your own

Tool transfer

A production site is closed or a product is taken over from a different company. The reasons for tool transfers vary widely and the transfer itself can be a challenging task. We support you in this and would be happy to use your tools in our injection-molding production.

Feasibility studies

The implementation of complex components and assemblies requires a detailed preliminary consideration of the project and interfaces. One example of this is the derivation of an injection-molding tool concept on the basis of a component’s 3D model. Albeit such an analysis can also be a multi-step manufacturing concept (injection molding of several articles as well as a downstream ultrasound welding process with purchased parts and laser marking) and include the logistics chain.

Substitution metal > plastic

Lightweight design, MR compatibility, cost reduction – all of these are reasons to substitute metals in favor of plastics. With the help of additives, it is possible to modify plastics in such a way that facilitates very high tensile loads, for example. Likewise, plastic-based solutions allow for cost-effective large series production, which, in the case of individual production of metal components, is only possible to a certain degree.

Design of multi-use to single-use articles

Another trend in the area of medical products is the shift from multiple use, e.g. of instruments, to single use. Here, too, we can achieve material key figures that come close to those of metals by implementing individual plastic modifications.

In the case of complex projects, e.g. the implementation of single-use endoscopes, we have extensive experience in the areas of injection molding and extrusion as well as assembly for the production of high-performance yet cost-effective solutions.

Regulatory support – we know the provisions

Process validations

In order to guarantee the safe production of medical products, we have designed our process landscape and documentation in such a way that allows us to validate production steps which are deemed critical. This can be the validation of the injection-molding process, or that of an adhesive bonding/welding work step or the bioburden load. Process validations and the respective specific scope of service are defined in advance with our customers.

Manufacturing instructions and article-specific tests

For the implementation of complex assemblies involving the use of a range of established joining processes, we create individual manufacturing instructions, for instance, on the result of process validations. This also involves specifying test steps and test processes which are to be carried out in the course of a series.

FLEIMA-PLASTIC

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