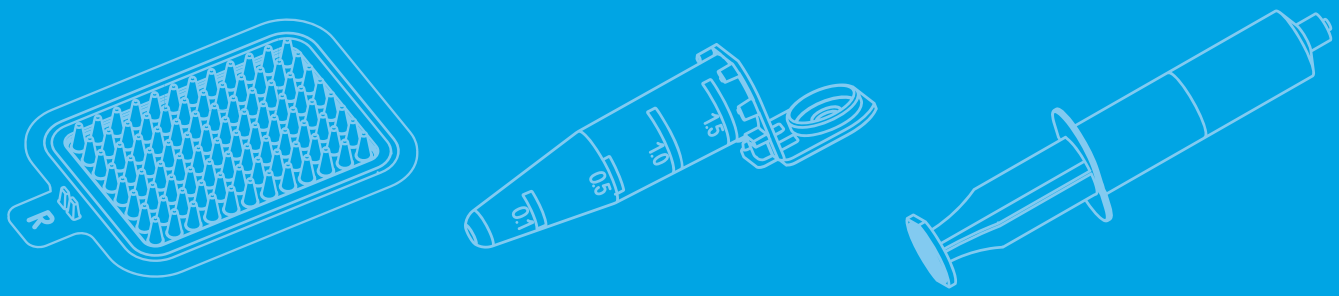
GEMÜ®

GEMÜ Medical

System solutions from the cleanroom



Plastics processing
in the cleanroom

Cleanroom manufacturing from a worldwide system provider

GEMÜ Group

1964
founded

over **1700***
employees worldwide, a presence
in more than 50 countries,
27 subsidiaries,
six manufacturing sites

* (As of 09/2017)

The GEMÜ Group is a leading manufacturer of valve, measurement and control systems and employs over 1700 members of staff worldwide. With six manufacturing sites and 27 subsidiaries, as well as a closely linked network of commercial partners, GEMÜ is now active in over 50 countries on all continents. GEMÜ is the world market leader in sterile valve applications in the pharmaceutical and biotechnology industries.

The GEMÜ range of services for complex system solutions

Systems from GEMÜ are used in process engineering and adjacent fields of activity in the following industrial sectors:

- *Medical industry*
- *Pharmaceutical, biotechnology and cosmetics industries*
- *Microelectronics and semiconductor industries*
- *Beverage and foodstuff industries*
- *Chemical and environmental engineering industries*
- *Water treatment industry*
- *Machine, apparatus and plant engineering industries*

GEMÜ Medical

GEMÜ Medical was founded in 2003. As a supplier for medical technology companies and pharmaceutical producers, GEMÜ Medical produces customized plastic solutions for surgical instruments, lab accessories and other medical instruments and devices. International customers receive individual components, packaged and inspected assemblies and sterile finished products for immediate use in the medical industry.

To guarantee growth and compliance with the strict requirements for the production environment, the new plant for cleanroom manufacturing was opened in Emmen in September 2012.

Our markets

We supply our plastic solutions globally to the medical industry. They are used in the following market segments: Drug delivery, medical devices, diabetes care, disposables, laboratory equipment.

Emmen cleanroom plant

In September 2012, GEMÜ Switzerland opened its new cleanroom manufacturing plant. The plant is in Emmen, in the canton of Lucerne. It uses the very latest manufacturing technologies and achieves cleanroom quality in accordance with ISO class 8 (in operation) as well as GMP class C. This level of quality applies to the entire manufacturing process – from material supply via production to subsequent assembly and packaging.

Customer solutions

The new cleanroom plant has provided GEMÜ with much higher capacities for the manufacture of medical industry products. This enables you to benefit even more from GEMÜ's extensive experience and comprehensive expertise in the cleanroom processing of plastics. A particular focal point is the manufacture of system solutions for the medical industry.

Your contact for customer solutions:

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Customer solutions
for the medical industry

Highly efficient manufacture of plastics solutions in a state-of-the-art cleanroom

As a supplier for medical technology companies, GEMÜ produces customized plastic solutions for surgical instruments, lab accessories and other medical devices. You receive individual components, packaged and checked sub-assemblies and sterile finished products for immediate use in the medical industry. The cleanroom plant at Emmen offers the following performance parameters:

Cleanroom capacity

- *Approx. 1800 m² cleanroom ISO 8 (in operation) and GMP class C for injection moulding*
- *Approx. 1000 m² cleanroom ISO 8 (in operation) and GMP class C for assembly technology; locally, this area can be increased to ISO 6 (in operation)*
- *An additional 2500 m² are available for injection moulding and assembly technology under controlled ambient conditions (hygiene sector)*

Injection moulding technology

- *Injection moulding machines with closing force of between 35 tons and 220 tons*
- *Parts weight ranging from approx. 0.1 g to 600 g*
- *Wide range of equipment for processing fluoroplastics*

Assembly technology

- *Automatic assembly systems and assembly stations*
- *Manual assembly of semi-finished products through to checked finished products by specially trained cleanroom staff*

Our cleanroom expertise

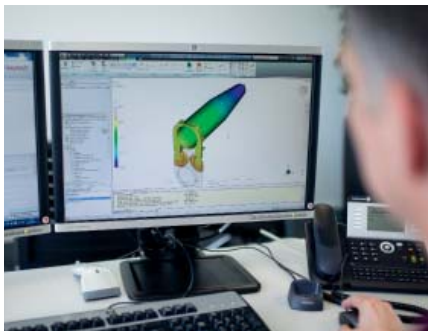
- *Injection moulding*
- *Assembly*
- *Packaging*
- *Printing*
- *Plastic welding*
- *Ready-to-sterilize (RTS)*
- *Sterile finished products*

Additional expertise

- *Mechanical processing*

Manufacturing expertise
in the cleanroom

Injection moulding, assembly, engineering, tool manufacturing and logistics



Plastics engineering

You can take advantage of GEMÜ's expertise in the cleanroom processing of plastics in the following areas:

- *Advice on the replacement of metal components with plastic*
- *Optimization and simplification of existing designs for manufacturing with plastic with the help of 3D-CAD (Solidworks) and FEM (Finite Element Method)*
- *Support in the selection of appropriate materials*
- *Simulation of the injection moulding process using Moldflow® tools*
- *Procurement and manufacture of functional prototypes and test samples using rapid prototyping*
- *Conceptual design and procurement of injection moulding tools*

Tool manufacturing

GEMÜ's own tool manufacturing department enables short reaction times. We develop, design and construct the tool for you and also assume responsibility for maintenance and modifications. In addition, we work with the GEMÜ parent company in Germany as well as with external tool suppliers, making sure that we always find the optimum solution for you.

Cleanroom injection moulding

We use injection moulding machines in our cleanroom with ISO class 8 (in operation) and GMP class C to manufacture your product efficiently and precisely. GEMÜ specializes in the processing of demanding high-temperature plastics, the integration of inserts and multiple component injection moulding. Thanks to additional flow-box systems, processing can be achieved locally that is one class higher. Using a central drying and conveying system, the raw material is fed in directly with minimal contamination.

Cleanroom assembly

For assembly, GEMÜ achieves class 8 (in operation) and GMP class C values in accordance with ISO 14644-1. In addition to assembly in this environment, washing, testing and packaging work is also carried out. The assembly work is supported by the strategic use of automatic assembly systems.

RTS

Our state-of-the-art cleanroom concept enables us to manufacture ready-to-sterilize products. Thanks to additional air and hygiene measures installed around the manufacturing cell, we are able to manufacture components using injection moulding that fulfil the requirements of GMP class B.

Logistics

Based on decades of experience, the assembly of mechanical and electronic components has become one of our core competences. We are very happy to work with you to develop a specific packaging concept. Tailored to your needs, GEMÜ offers you a flexible logistics solution for outline agreements.

Qualification and validation

Manufacture of medical industry products

Safe and validated processes

GEMÜ performs a risk assessment for your product using the FMEA (Failure Mode and Effect Analysis) method and in accordance with the EN ISO 14971 standard. This includes investigating the system risks of the operating equipment and the process risks involved with manufacturing. We also provide you with information and recommendations with regard to potential design risks. These subjects are covered in the risk file for your project. This is continuously updated. At the same time, the measures defined in the file are monitored.

Four steps for qualifying operating equipment

Qualification enables GEMÜ to deliver documented proof that an operating equipment satisfies the necessary requirements. Qualification comprises four stages: Design Qualification (DQ), Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ). The final qualification report documents observations, findings and any outstanding measures. As a result, the design can be fixed and all production papers approved. At the same time, release is given for validation.

Process reliability through multiple validation runs

Validation provides documented proof that the processes for manufacturing your medical industry product are safe and can be permanently guaranteed. For the process validation, the series product is manufactured in three separate batches. The batch size of the validation runs is determined by the desired quantities. If necessary, a larger test quantity can be agreed to analyze compliance with critical quality criteria. Following successful implementation, the qualification and validation phase is completed with a final report and, if required, an update of the FMEA.

GEMÜ can provide support for additional services to validate your product using its extensive partner network. This includes the following options:

- *Packaging validation*
- *Transport validation*
- *Ageing tests*
- *Sterilization validation*
- *Biological qualification*

Basic standards for qualification and validation

- *EN ISO 13485*
- *EN ISO 14971*
- *MDD 93/42 EEC*
- *21 CFR820*
- *EU GMP guidelines*

Our references

Customer solutions from the cleanroom

Specific products for the medical industry

From individual manufacture *to series production*

The process for the optimal cleanroom product

At GEMÜ, projects comprise five phases. The end of each phase is a milestone; it contains a review as well as the release for the next phase. Customer solutions primarily begin in phase three.

Phase 1: Concept

The requirements for the new product are defined in the user specification. Design and concept variants are then created. Patent suitability is clarified and the preliminary regulatory strategy and risk and cost analyses are compiled.

Phase 2: Product development

For more detailed project planning, the user specification is developed into a performance specification. Once approval is given, product development begins. CAD data is generated and prototypes are constructed. The production process (including test planning) is planned. The marking and packaging of the product are defined.

Phase 3: Process development

In the process development phase, the tools, fixtures and models are designed, manufactured and sampled. At the same time, the qualification processes are implemented. Production guidelines are drawn up and staff are given appropriate training. The process development phase ends when the functional capability of the tools, fixtures and plants has been qualified.

Phase 4: Process proof

The proof phase starts with the design, the document freeze and commencement of change management. Process proof is provided using three validation runs. Series production parts are manufactured and tested in accordance with the process documentation in a batch size that is similar to series production levels. If required, a larger test scope can be set up. Following validation, the product is registered and released for production.

Phase 5: Market launch

Following the final project review, the product is introduced to the market.

Measures to secure
the highest level of cleanroom quality

Our certifications and our quality management

In the cleanroom plant at Emmen, all products are subject to continuous quality management and consistent monitoring. Tests carried out by independent test laboratories and users ensure that the cleanroom quality is consistent and reproducible:

- *Use of specified raw materials with continuous incoming inspection*
- *SPC – statistic process control and reference sampling*
- *Creation of initial sample test reports (ISTR) before component approval*
- *Continuous further development for staff and continuous improvement process*
- *Voluntary supervision and customer audits – certified in accordance with ISO 9001 and ISO 13485*

Defined and certified quality

GEMÜ works with you to define the requirements for the new product.
This includes implementation of the following measures:

- *Samples are taken of all raw materials, tested to ensure that they satisfy the required specifications and kept in safe storage for years to come*
- *The plant is subject to constant monitoring and requalification*
- *Qualified operating equipment and validated processes*
- *Cleanroom production employees are regularly trained and tested*
- *A 100% test can be carried out on the products if required*
- *Customer audits are used for optimization and valuable feedback*
- *In the interests of traceability, all manufacturing documents and reserve samples are archived according to the defined storage period*

All current certificates can be found on our website at
www.gemue.ch

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