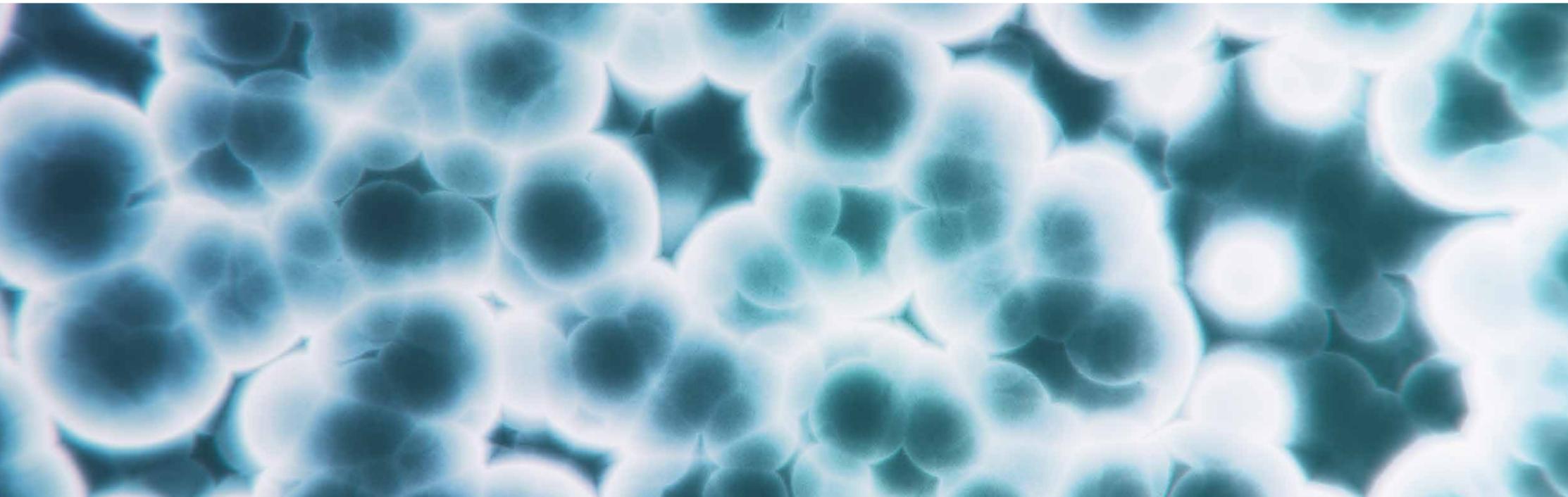




LIFE SCIENCE
Solutions for the Manufacturing
of Medical Technology Products.



Protecting life from head to toe.



More than 60 years experience

The Weiss Technik companies belong to the worldwide active Schunk Group and consist of the branch companies Weiss Klimatechnik, Weiss Umwelttechnik, Vötsch Industrietechnik and Weiss Pharmatechnik. The latter specialises in the development of technical products and processes for the pharmaceutical, chemical and cosmetic industries.

Life Sciences analyse the processes and structures of living organisms. The objectives are the protection and improvement of life through the development and production of new medicines, optimised medical products, and individualised therapies. With technical products and customised solutions, we support businesses, laboratories, and research institutes in achieving these objectives safely and sustainably.

Partner for production and research

We have comprehensive technical knowledge and in-depth competence in this field. With this experience, we enable our customers to implement scientific discoveries successfully, ensure safer and more reliable production, and improve product quality continuously. As a reliable partner of research and industry, we have been setting new standards for more than 60 years.

Environmental, heat, climate control and pharmaceutical technology

Our multifaceted and proven range of products and services includes special solutions for personnel and product protection, clean room and stability testing, hot air sterilisation, tensile tests of materials, and phytomedicine. Our solutions meet or exceed all relevant directives, guidelines, and industry standards. Furthermore, we offer our customers an individually customised service programme, from development to after-sales service.

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Safe solutions for the manufacturing of medical technology products.



HEAT TECHNOLOGY

- Tempering ovens for silicones and plastics
- GMP-compliant heating and drying chambers
- Vacuum dryers
- Microwave systems
- Annealing ovens



CLEAN ROOMS AND MEASURING ROOMS

- New construction and renovation of complete clean rooms
- Ventilation and air conditioning technology
- Measuring technology and monitoring
- GMP* qualification/re-qualification
- New construction and upgrade of measuring rooms in compliance with VDI/VDE 262



CONTAINMENT SYSTEMS

- WIBOjekt® laboratory work stations
- WIBObarrier® laboratory work stations



TENSILE TESTS FOR MATERIALS TESTING

- ETE and EKE climate chambers



SERVICE

- Consultation and maintenance
- Spare parts management
- Energy optimisation
- Instruction and training
- Qualification and re-qualification

*GMP (Good Manufacturing Practice)



Creating safe production conditions.

Innovative and individual heat technology for the highest requirements.

The highest requirements in regard to quality and hygiene must be met when manufacturing medical technology products. Proven and reliable heat technology is indispensable in protecting patients, reliably preventing quality deviations and maximising economic efficiency in production.

Flexible use of heat technology

Our range of products comprises vacuum dryers, microwave systems, annealing ovens and GMP-compliant clean room solutions. Depending on requirements, we deliver classic chamber ovens or high-efficiency continuous oven systems for high-volume production.

Our ovens are designed for many applications, including heat treatment of surgical needles, plastic tubes and vaporisers for inhalation. They are used in the production of eyeglass lenses and contact lenses, implants, prosthetics and stents. They are also used in the dental industry for the production of dental crowns.

Your advantages

- Qualitatively high-quality results
- Reduced process times
- Increased capacities
- Gentle heating processes
- Reproducible processes
- GMP-compliant device designs

Using efficient technologies.

Proven and tested heat technology for sensitive products.

Reliable heat technology is a prerequisite for meeting the requirements on medical technology products. This is why we provide our customers with equally innovative and sophisticated technologies for safe, efficient and economical production.

Vacuum dryers for sensitive materials

Temperature-sensitive materials like surgical needles require special drying processes. **vötschtechnik®** vacuum dryers ensure these conditions are met by means of lowered boiling points and shortened drying times.

Other advantages:

- Gentle drying of heat-sensitive materials
- Shortened drying times by lowering pressure
- No oxidation processes
- Recovery of vaporised liquids
- No turbulence (ideal for light-weight, powder products)

Microwave systems for filter drying

The manufacture of medical technology products like dialysis filters requires high-precision processes. Our microwave systems offer reliable accelerated and more economical processes by ensuring quick and energy-efficient drying. Energy needs to be applied only to the filter that will be heated; the drying system itself remains cold.



Annealing ovens for various materials

The annealing ovens of the VAW series are designed for various heat treatment processes in medical technology. One example is the production of surgical needles. The operating principle of annealing ovens has been tested for decades and we are continuously developing this principle. Nominal temperatures range from 500°C to 750°C, depending on the version.

GMP-compliant clean room solutions

Quality assurance has a central function in medical technology and in pharmaceutical manufacturing. GMP-compliant quality management satisfies the requirements of health authorities and ensures product quality. We offer our customers special stainless steel versions of our devices tailored to requirements of the industry. They are compliant with GMP guidelines and are designed for use in clean rooms of the respective ISO classes.





Example application: starlim//sterner, Austria.

Economical silicone tempering of large batch sizes under clean room conditions.

Tempering is an important process in the manufacturing of products made from silicone elastomers. This process has to take place under clean room conditions to eliminate particulate loads and bioburdens in life science products. The silicone producer specialised in mass production starlim//sterner uses process-optimised standard tempering ovens made by vötschtechnik® for this process.

Process-reliable tempering of injection moulded parts

To guarantee optimum use of injection moulds and ensure the best possible product quality, silicone parts are post-cured in a tempering oven after moulding. The oven heats the products to the exact post-vulcanisation temperature of silicone for a precisely defined time. The time period is defined by statutory requirements for medical devices and by individual customer requirements. Defined amounts of fresh air are needed for the tempering process. At the same time, by-products, some of which can be combustible, must be reliably extracted.

High operational safety through customised standard solution

In the search for an experienced and competent partner for a tempering oven in the clean room, starlim//sterner decided to turn again to Vötsch Industrietechnik. One reason was because the company has a proven and technically sophisticated standard range of ovens. Another was that the use of products from the brand vötschtechnik® has proven its value time and again in recent years.

The challenging aspect of this project was the integration of the oven in the ISO 8 clean room, in compliance with DIN EN ISO 14644-1. A standard VTU 125/200 oven equipped with high-quality components was selected to meet this challenge. The oven has a heating power of 36 kW and a rated temperature of 300°C. With these specifications, it delivers extremely high process consistency.

The oven design was modified to ensure optimum connection to the clean room. The entire oven system with easily accessible maintenance elements can be accessed from the grey room. This simplifies servicing and reduces downtimes.

The tempering oven is equipped with a loading trolley with two electrically operated rotating drums. These components ensure high efficiency when tempering of large unit numbers, which was a key purchasing criterion for starlim//sterner. The use of a rotating drum trolley facilitates ergonomic loading/unloading. During the process, the drums rotate slowly to prevent the parts from influencing each other mechanically and to ensure even heat distribution. Since some combustible vapours can be released during the process, a reliable air intake and outlet system is crucial for safe operation.

Fully automatic control through ERP system

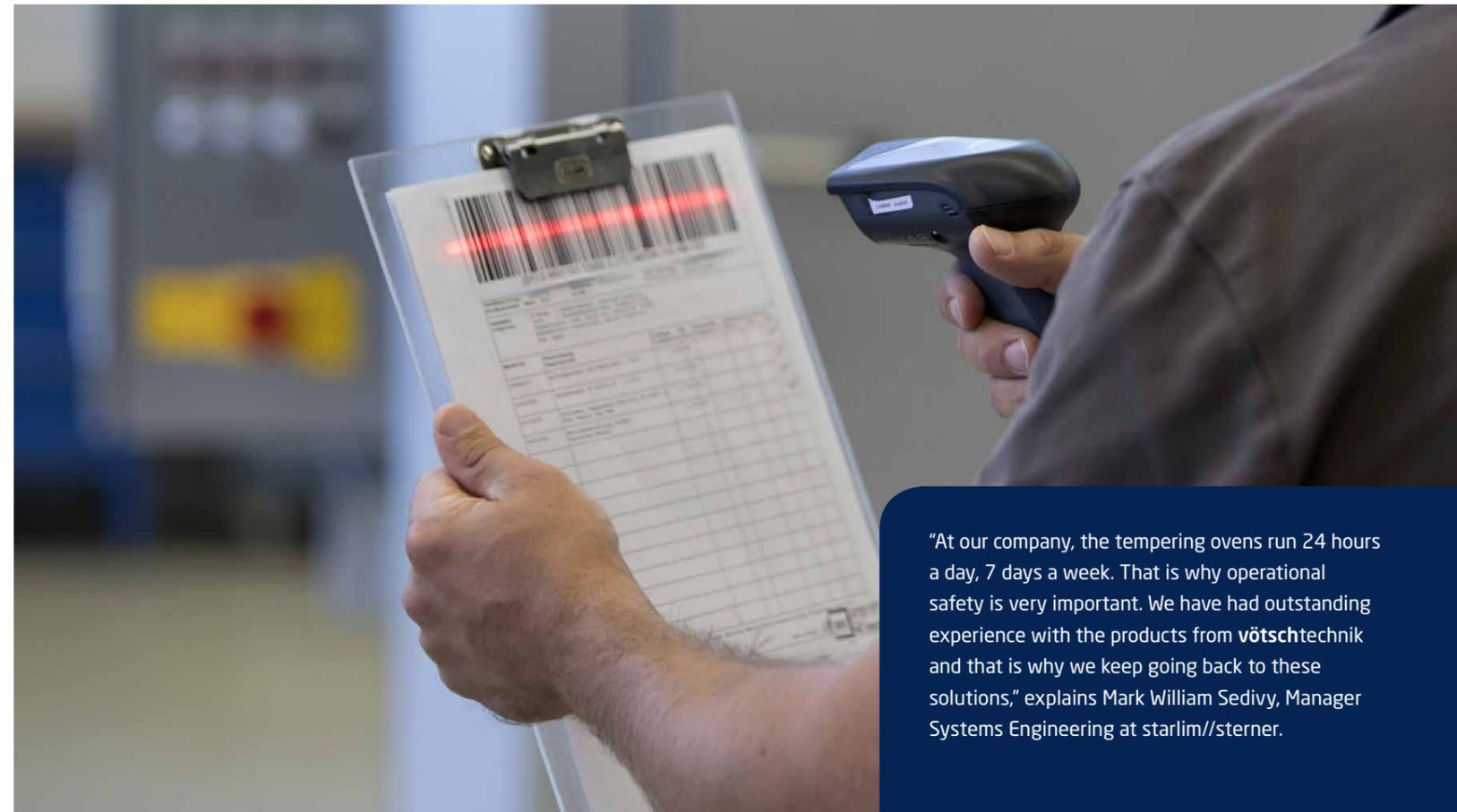
The ovens have a **vötschtechnik®** SIMPAC control system and linked together through the SIMPATI software with connected barcode scanner. The software is connected to the in-house ERP system. This ensures complete process transparency at all times. It also relieves employee workload and increases quality since all relevant settings are made automatically and are standardised.



This is a huge advantage because starlim//sterner uses the oven to temper a wide range of products like seals and moulded parts for medical technology with different process times and temperatures. At the end of the process, an automatic message is created for the ERP system, enabling simple and comprehensive documentation of production.

starlim//sterner—silicone at its best

The international starlim//sterner group of companies specialises in tool making and injection moulding of small silicone parts. The group's products are used, among other things, in the automotive industry and in medical technology. Producing nine billion parts per year, the company has a clear focus on mass production. Worldwide the starlim//sterner Group currently operates 22 tempering ovens of the **vötschtechnik®** brand. Four of them were delivered within the last year alone.



"At our company, the tempering ovens run 24 hours a day, 7 days a week. That is why operational safety is very important. We have had outstanding experience with the products from **vötschtechnik** and that is why we keep going back to these solutions," explains Mark William Sedivy, Manager Systems Engineering at starlim//sterner.

Ensuring medical technology production.

Technology and service for clean room solutions conforming to standards.

Clean production conditions are extremely important in the manufacture of medical technology products and primary packaging; the statutory requirements on clean room technology are correspondingly stringent. With many years of experience, we offer our customers sophisticated products, individual solutions and reliable services for their clean rooms.

Clean rooms from one source

Our clean room technology gives our customers the highest level of safety and maximum protection against contamination. This is important above all in the medical technology industry with particularly high requirements on cleanliness and precision. For example, the production and acceptance testing of stents, implants and primary packaging has to take place under clean room conditions.

Individual solutions

The technical and legal requirements on clean rooms are product-dependent. For this reason, we design, produce, deliver and qualify turnkey clean rooms in accordance with standards, tailored precisely to customer requirements. These permit reliable production and reliably fulfil all the necessary safety requirements. In addition, we modify the existing clean room systems to suit the customer's need or we make necessary upgrades.

Our products and services

- Newly built clean rooms and upgrade of clean rooms
- Ventilation and climate control
- Measuring technology and monitoring
- GMP qualification
- Customer-specific solutions
- Servicing, maintenance and repairs

Product range.

Proven special solutions for pharmaceutical production.

The installation of a GMP* clean room requires the close collaboration of customer, planning specialist, manufacturer and responsible supervision authority from the first step of planning. We ensure smooth-running collaboration, from concept to handover of the turnkey, qualified clean room.



Made-to-order clean rooms

As a specialist in climate control, we furthermore ensure that clean rooms are airconditioned. Our units are exactly matched to the installation concept and offer the advantages of energy saving and reduced running costs.

Monitoring and GMP qualification

Clean rooms must be reliably clean – at all times and everywhere. For this reason, the qualification of installations and areas in pharmaceutical use is obligatory and a central part of Good Manufacturing Practice (GMP). With our innovative measuring techniques, we record, monitor, and document the critical parameters of the clean room operations. Particle detectors count and identify the smallest particulate contamination. If a defined threshold is exceeded, an alarm is triggered.

To avoid risks and ensure the qualified status of the installation in the long term, our service experts regularly service and test all relevant items. Together with our qualification team, they also ensure that the operation of the clean room is compliant with all legal requirements.



Personnel and materials air locks

Clean room air locks are designed to control the entry and exit of persons, materials, and products between areas with differing cleanliness classes and pressure levels. To prevent contamination of the clean area by airborne particles, only one door can ever be opened.



Example application: Zimmer Biomet.

Air conditioning, clean room and heating technology for medical implants.

Medical device company Zimmer Biomet located in Winterthur, Switzerland, is one of the world's leading manufacturers of orthopaedic implants. The quality of artificial hip or knee joints depends on the precision of the manufacturing processes. Before an implant may be used, it must be tested precisely in the weisstechnik measuring room we delivered.

Creating constant measuring conditions

Zimmer Biomet tests each individual joint in special 3D coordinate measuring machines. For this purpose Zimmer Biomet uses a special measuring room designed, built and commissioned by weisstechnik.



Meeting technical requirements

The requirements on measuring rooms of accuracy class III are found in Guideline VDI/VDE 2627. This guideline defines, for example, the ambient conditions that must be observed and the spatial and time tolerances for temperature. To avoid measuring errors and false results, finished hip joints must be brought to exactly this temperature prior to measurement. This condition is ensured through several hours of storage in an anteroom.

Room-in-room concept

Previously, every measuring machine was located in a separate room. Temperature fluctuations occurred because no airlocks were available. This frequently resulted in inaccurate measurements that had to be repeated. In the new, large measuring room, temperature-controlled airlocks reliably prevent fluctuations in room climate. Our compact air conditioning unit is, therefore, installed outside of the measuring room. Special sensors measure and transmit continuously temperature and moisture readings and provide proof for each product that the product was measured within the required specification.



"The measuring room is brightly illuminated equally with 1,000 lux is encapsulated by thermally isolated enclosure areas," explains Hans-Joachim Weitzel, Project Manager Cleanroom division. "In this way, our room-in-room concept creates constant conditions."

Increasing workplace safety.

Reliably protecting personnel, products and processes.

In some areas of medical technology, materials are used that can endanger the health of personnel. In addition, it is also important to protect the products from contamination. With the weisstechnik® WIBObarrier® and WIBOjekt® safety work stations, we guarantee maximum protection for people and the product.

We develop, build and distribute safety work stations in numerous standard versions. The versions can be modified to meet individual customer requirements and accessories can be added.

Our products and services

- Safety work stations
- Clean air curtain technology
- Customer-specific solutions
- Consultation, design and execution
- Servicing, maintenance and repairs

Systems and applications.

Proven system solutions for demanding applications.

With our WIBOjekt® and WIBObarrier® principle, we create the optimum basis for reliable protection at the workplace. The systems are scalable and can be adapted to individual requirements.

WIBOjekt® principle

WIBOjekt® safety work stations reliably protect products, personnel and the whole working environment. To do so, a clean air curtain is generated by specially shaped air outlets. This curtain reliably traps hazardous pollutants, such as gases and airborne product particles and transports them to the exhaust outlets.

This allows the work to be carried out with unimpeded access. Even if the user reaches through it, the air curtain remains basically stable and protects personnel as well as the ambient room from escaping emissions.

The WIBOjekt® air system generates considerably less exhaust air volumes despite the very high capture and exhaust quality than conventional extraction systems and reduces the operating costs significantly.



WIBObarrier® principle

Our WIBObarrier® safety work stations were developed for the special requirements in the manufacture of medical technology products. They employ a three-zone principle. The outlet nozzles incorporated in the front area of the hood generate a stable clean air curtain. This separates and protects personnel, products and the surrounding area. Furthermore, this curtain reliably traps particles that are released by personnel conducting work in the working area. In the product area itself, a barrier curtain draws in escaping particles and conveys them directly to the suction openings. The product is effectively protected from contamination.

In the development of the WIBObarrier® systems, great emphasis was placed on keeping product exposures within OEL* levels and on clean air qualities in accordance with DIN EN ISO 14644-1. The systems are available in closed (CCS, Closed Containment System) and in open (OCS, Open Containment System) forms.



*OEL (Occupational Exposure Limit)

Reliably ensuring durability.

Tensile and materials testing under all climatic conditions.

Medical devices, like a prosthetic leg or arm, must be robust. They also have to withstand the high dynamic loads generated by movement. Special material test machines are used to determine whether the products meet these high demands.

Special solutions for medical technology manufacturers

Building on our ETE and EKE climatic chambers, we develop special solutions to satisfy the requirements of our customers. The solutions can be adapted exactly to the respective products and test requirements and are ideally suited to reliably test the quality of medical technology products.

Widely differing climatic zones possible

At the press of a few buttons, any climatic zone in the world can be set up for simulation. Measurements at various temperatures and humidities in combination with pressure, tension, bending and ageing yield exact information on the material behaviour and quality of any packaging.

Standard climatic chambers

We supply our customers with three standard models in the series ETE and EKE:

- E type:** compact model with machine in the rear area
- C type:** versatile chamber on floor rails
- M type:** separate test chamber and machine room with flexible line adjustment

The climatic chambers are available in various sizes and versions. They can be equipped with numerous standard features and many additional options.

Our products and services:

- Reliable test machines
- Adjustable for any climate
- Ease of operation
- Servicing, repairs and after-sales services



Acting effectively, worldwide.

We think and act with service in mind. Our customers see us as partners. With our specialised service departments, we provide you with lasting solutions for a long and successful collaboration.



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Advice

Take advantage of our many years of experience. Our knowledgeable experts are ready to support you in word and deed, by telephone or on the spot, in every step of your project, from the first idea to after-sales service.

Servicing and maintenance

We adapt our service offers exactly to our customers' requirements. Our full maintenance service provides maximum security with fixed, calculable costs. We offer various service levels with guaranteed response times of no more than 24 hours after the occurrence of a fault.

Spare parts management

Thanks to our extensive stock-keeping, many spare and wearing parts are available reliably and at short notice. To further increase operating reliability, it can be a good idea to keep an additional stock of selected spare parts on site. We would be pleased to advise you further.

Qualification and re-qualifications

We provide our customers with all qualifications and re-qualifications necessary for the reliable operation of an installation. These include DQ, FAT, OQ, SAT, IQ, and GMP.

Clean room technology

For production under clean room conditions, we offer the preparation of the legally prescribed regular evidence of the correct operation of the systems. Our specialists take on all the required tasks - from weak-point analysis, through filter tests, to monitoring.

Energy optimisation

With the optimisation of an installation, we increase its performance and raise the energy efficiency. The energy inspection for air conditioning systems is a legal obligation in Germany according to the Energy Saving Ordinance (EnEV) 2009. Our energy check meets these legal requirements.

Training

We carry out regular service training sessions, free of charge. Furthermore, our experts train our customers' personnel. The content and duration of the training sessions are adapted to particular wishes and requirements. We would be happy to discuss the possibilities with you and make a non-binding offer.

weisstechnik

Test it. Heat it. Cool it.

Our solutions are deployed around the world in research, development, production and quality assurance of numerous products. Our experts from 21 companies are at your service in 14 countries, ready to provide support to ensure high operational reliability of your systems.

Weiss Umwelttechnik is one of the most innovative and significant manufacturers of environmental simulation systems. With these testing systems, we can simulate all climatic conditions around the globe and beyond, under accelerated conditions. Whether temperature, climate, corrosion, dust or combined shock testing: We have the proper solution. We supply systems in all sizes, from standard versions up to customised, process-integrated facilities - for high reproducibility and precise test results.

Vötsch Industrietechnik, a subsidiary of Weiss Umwelttechnik, offers a wide product portfolio in the field of heating technology. With an experienced team of engineers and designers, we develop, plan and produce high-quality and reliable heating technology systems for virtually any field of application. Products include heating/drying ovens, clean room drying ovens, hot-air sterilisers, microwave systems and industrial ovens. The portfolio reaches from technologically sophisticated standard versions to customised solutions for individual production operations.

A further Weiss Technik company, Weiss Klimatechnik, also offers reliable climate solutions wherever people and machinery are challenged: in industrial production processes, hospitals, mobile operating tents or in the area of IT and telecommunications technology. As one of the leading providers of professional clean room and climate solutions, we deliver effective and energy-saving solutions. Our experts will guide you from the planning to the implementation of your projects.

Weiss Pharmatechnik, a subsidiary of Weiss Klimatechnik, is a competent provider of sophisticated clean room and containment solutions. The product range includes barrier systems, laminar flow facilities, security workbenches, isolators and double door systems. The company emerged from Weiss GWE and BDK Luft- und Reinraumtechnik and has decade-long experience in clean room technology.

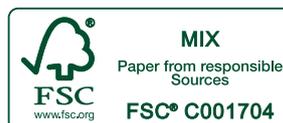
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Because environment and climate are more to us than just a part of our name.



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