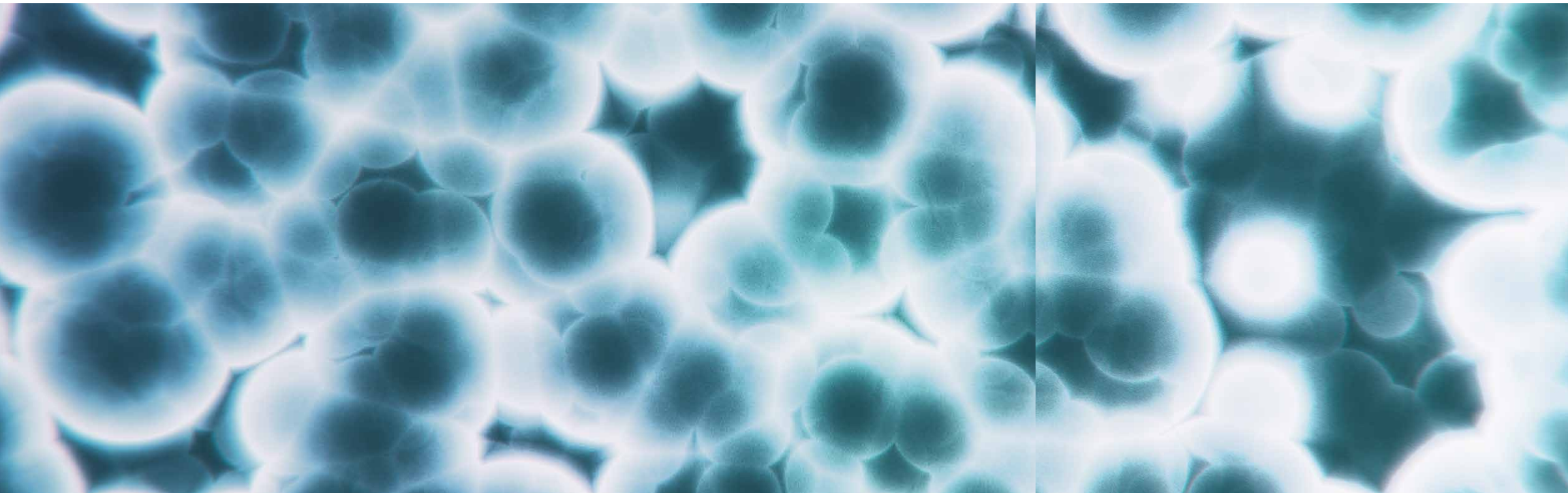




LIFE SCIENCE Products
for the pharmaceutical industry.



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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Diversity of solutions for special working conditions.

PERSONNEL AND PRODUCT PROTECTION

- WIBObarrier®
- WIBOjekt®
- WIBOjekt® economy
- BDK laminar flow work benches
- Isolators
- Filter fan units



CLEAN ROOMS

- Turnkey clean rooms
- Clean room work stations
- Ventilation and climate control
- Air lock systems
- GMP qualification
- Compact climate control units



STABILITY TESTING / PHOTO-STABILITY TESTING

- Pharma 280, 600, 1300, 2000
- Pharma 250L, 500L
- Walk-in test chambers
- Standard-climatic cabinets for special applications



HEAT TECHNOLOGY

- Hot air sterilisers VHS, VHSF
- Clean room heating and drying cabinets VTF
- Vacuum dryers VVT
- EX dryers VFT 60/90, VTUW



TENSILE TESTS FOR MATERIALS TESTING

- Climatic chambers ETE und EKE



PHYTOMEDICINE

- Fitotron® SGC, HGC, SGR, CGR





Increasing workplace safety.

Reliably protecting personnel, products and processes.

In the field of personnel and product protection, we develop and manufacture technically advanced clean air and containment systems for laboratories, research institutes and the chemical and pharmaceutical industries.

Customised, innovative, reliable

Our customers benefit from our many years of experience in finding solutions for the widest range of special demands. We adapt our products to individual requirements. If need be, we develop and produce new technical solutions. These protect personnel from hazardous substances and secure products against contamination.

Our products and services

- Product and personnel protection
- Safety and laboratory workstations
- Clean air curtain technology
- Advice design and execution
- Servicing, maintenance and repairs

Systems and applications.

Proven system solutions for demanding applications.



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

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 EN ISO 14644-1. The systems are available in closed (CCS - Closed Containment System) and in open (OCS - Open Containment System) forms.

The Weiss WIBObarrier® principle

Our WIBObarrier® safety workstations were developed to meet the special requirements for the decanting and filling, product sampling and weighing out of pharmaceutical products. Individual accessories can be included as needed.

The WIBObarrier® safety workstations use 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, it traps reliably 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.

WIBOjekt® principle

WIBOjekt® safety workstations protect reliably products, personnel and the whole surroundings. To do so, a clean air curtain is generated by specially shaped air outlets. This traps reliably hazardous pollutants such as gases and air-borne product particles and carries them to the exhaust intakes in the rear wall.

WIBOjekt® workbenches and free workstations

The workbenches and free workstations are available in various versions and with numerous add-on options. In the hood, the rear wall, and/or front edge of the bench, these are fitted with WIBO® ejector nozzles. These are exactly matched to one another in design, shape direction and setting and generate a clean air curtain.

The filters are compactly incorporated over the whole rear wall. The large incident flow surfaces ensure low filter loading. The filters can be easily and conveniently changed from the workstation side. The direct uptake and cleaning of the contaminated exhaust air prevents long exhaust paths, the accumulation of pollutant deposits, and cross-contamination.



Systems and applications.

Further special systems for personnel and product protection.



Weiss WIBOjekt® economy safety and laboratory workstations

The WIBOjekt® economy safety and laboratory workstations are ideally suited for personnel and/or area protection and precisely adapted to the particularly strict safety regulations in laboratories. The safety workbox operates according to the patented WIBOjekt® controlled airflow principle. This forms a stable clean air curtain and thereby permits safe working with hazardous substances.

The housing and framework are made from a resistant aluminium alloy, which is anodised and manufactured with a sophisticated coating for additional corrosion protection. WIBOjekt® economy workstations are available in various versions including, if need be, clean room or EX protection.



Isolators

Isolators are needed whenever a controlled atmosphere, isolated from the surroundings, must be established and, at the same time, high product and/or personnel protection are required. Examples are microbiology laboratories, solids processing, and active ingredient production.

Depending on the application, isolators are operated with negative pressure for personnel and environmental protection or with positive pressure exclusively for product protection. The double air locks for docking are available in four different sizes and are fully compatible with models from other manufacturers. Specially developed docking systems and glove access rings are included in the scope of delivery.



BDK laminar flow clean air workbenches

BDK laminar flow clean air workbenches are available in product protection and in product and personnel protection versions. Clean air workbenches are available with a choice of horizontal or vertical air displacement flow. Laminar flow clean air workbenches for product and personnel protection use the air circulation principle and are available only with vertical airflow in the work area.

For particularly high product protection, BDK laminar flow modules MVF and FFM can be combined to form installations of any size. All modules meet clean room class 5 requirements in compliance with ISO 14644-1 or cleanliness class 3 requirements in compliance with VDI 2083.



Example application: Swiss pharmaceutical manufacturer.

WIBObarrier® decanting station for high containment conditions.

Working with active ingredients requires a high level of safety. An especially high risk is attached to the introduction and the docking of containers. We supply flexible containment systems with the proven WIBObarrier® controlled airflow technology. This permits risk-free working, even with the front windows open.

Individually developed and produced

The WIBObarrier® decanting station was specially designed for the semi-automatic decanting and filling of pharmaceutical active ingredients and auxiliary agents up to OEB 5. It consists of a materials air lock for the introduction of the container, a decanting cabin for delivery of the products, a filling cabin with integral powder transfer system, and a docked container station with double flap system for filling the products.

Effective and flexible

The WIBObarrier® decanting cabin has two clear advantages for our customer, a large Swiss pharmaceutical manufacturer: It permits safe working and is sufficiently flexible for efficient processing. Personnel can access the full width of the cabin. At the same time, the pharmaceutical product is protected from contamination and purity is assured.

Ease of decanting under complex conditions

Powder substances are introduced into the protected area in one direction via roller track with materials air lock and interlocked lifting gates. Personnel can perform all work steps using the glove access ports with the front window closed. A lifting device with tilt function ensures convenient handling. Packages will be opened after they are transported in through the lock. With a suction lance, the contents are fed through a hose connection into the container of the vacuum conveyor and into the filling cabin. Below the container is the docked container station, which permits filling via a GMP-compliant double flap system. Personnel can add smaller quantities of pharmaceutical excipients through a hand valve with flange connected funnel. Larger quantities of excipients that do not pose a potential risk are fed through a second suction lance, directly from the delivery package outside the filling system.



Thanks to the innovative **weisstechnik** WIBObarrier® controlled airflow system, a high level of product protection is achieved. With the front window closed, the clean air is at least ISO 5 according to EN ISO 14644. Even with the front window open, the stable barrier curtain guarantees a safety level of OEB 4.

Protecting pharmaceutical products.

Custom clean room solutions for the widest variety of requirements.



For the production of pharmaceutical products, the top priority is air with a low particle count that is microbiologically pure. The real air purity requirements can vary significantly, depending on the product and the production process.

We plan, produce, deliver and qualify turnkey clean rooms in accordance with standards and precisely to customer requirements. These permit safe and secure production and reliably fulfil all the necessary safety requirements.

Our products and services

- Newly built clean rooms and upgrade of existing clean rooms
- Ventilation and climate control
- Air lock systems
- Monitoring and GMP qualification
- Servicing and maintenance

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.



*GMP (Good Manufacturing Practice)

Example application: Ursapharm.

Turnkey clean rooms for eye-drops and nose sprays.

As a producer of medicines, Ursapharm Arzneimittel in Saarbrücken must meet strict national and international quality requirements. Since 2002, the eye-drops and creams, and nose sprays have been produced with GMP-compliant clean room technology from Weiss Klimatechnik.

Highest cleanliness guaranteed

In the highly modern clean rooms, liquid medicinal products pass through a number of clean room air locks into clean room area A, where they are automatically filled into bottles. Our clean room installation, created specifically for this production process, was designed in such a way that it fulfils the requirements of the EU GMP Guidelines for classes A-D. Since the product is filled open, the highest cleanliness class is required: class A. Under these conditions and because of the patented pump and bottle systems, there is no need for the addition of preservatives.

Reliable clean room concept

The clean room cabins were built with special smooth, impervious, and abrasion-resistant wall and ceiling systems. Areas A to D are accessed via separate air lock systems for personnel and materials. The cleanliness classes C and D are met by means of turbulent, mixed ventilation. The incoming air passes through ceiling air vents with HEPA filters of class H14 in the clean rooms. Additional filter-fan units (FFUs) with HEPA filters ensure that the air change rates in the rooms are correct. The system achieves a high degree of mixing between clean air and room air and, at the same time, prevents draughts. The entire filling area in clean room area A in B is also equipped with FFUs.

Operational reliability guaranteed

In accordance with the rules of GMP, the clean room areas are divided into pressure steps. This prevents contaminated ambient air from getting into the clean room. Humidity, room pressure, air velocity, and temperature are monitored by a monitoring system installed independently of the climate control system. Remote monitoring of the installation is secured by an on-line alarm system. After the planning and completion of the project, we also took over responsibility for servicing the clean room, ventilation, and climate control systems. In addition to any maintenance work required, servicing also includes the initial qualification and re-qualifications required by GMP.

Made-to-order clean room climate control

Karl-Heinz Lotz, Head of Cleanroom Business at Weiss Klimatechnik: "When planning and designing the clean room climate control, we work very closely with our customers and planning experts. We know the requirements for personnel and material flows and the demands of a required GMP environment for the specific production processes of our customers."

Creating optimum test conditions.

Stability testing systems for pharmaceutical products.

In Germany, medicines are subject to particularly strict guidelines. If incorrectly stored, these products could lose their efficacy. The stability of active ingredients and medicines must therefore be demonstrated in long-term tests under defined climatic conditions.

Reliable testing technology

We supply our customers with dependable testing systems with which the stability of pharmaceutical products can be tested reliably and in accordance with the legal requirements. Our product range extends from laboratory-scale installations to walk-in climatic chambers for long-term tests. All systems have the necessary documentation possibilities in accordance with FDA 21 CFR part 11 and EU GMP (Annex 11) and meet the ICH guidelines Q1A and Q1B as well as national and international requirements. These include WHO, FDA and CPMP, amongst others.

Our products and services

- Climatic cabinets and walk-in climatic chambers for stability testing
- Photostability test cabinets
- Climatic change test cabinets
- Qualification and validation services
- Training, maintenance, and after-sales services



Reliably meeting all requirements.

Stability testing units for test laboratories.

We supply our customers with a comprehensive standard range of climatic cabinets and walk-in stability testing chambers. In addition, we plan and develop custom solutions for the widest range of volumes and constructions. Furthermore, we supply all the necessary services for the qualification and documentation of the installations.

Stability testing for laboratories

Our stability testing cabinets Pharma 280, 600, 1300 and 2000 were specifically developed to meet the requirements of stability testing laboratories. They cover all the basic requirements of the official recommendation and support a range of further special uses. For humidification, our systems work with a patented system that is permanently monitored by an electronics module. It produces sterile humidity, which is measured with a capacitive humidity sensor.

Reproducible temperature and climatic tests, directly at the workplace, are made possible with the extensive range of climatic cabinets. These particularly compact solutions have very high performance.



Photostability test cabinets

The photostability test cabinets Pharma 250-L and Pharma 500-L are outstanding for their ideal light, temperature and humidity distribution and deliver reliably reproducible light and climatic conditions.

The lighting installations meet the ICH guideline Q1B Option 2. They permit photostability tests to be completed in less than 100 hours. All samples are stored at the same distance from the light source and are uniformly irradiated by a special light/UV filter system. The additional installation of light and UV sensors permits recording of the irradiation values so that a light value integration can be carried out.



Reliable sterilisation.

Heat technology for the pharmaceutical industry.

Reliable heat technology ensures the particularly high quality requirements in the chemical and pharmaceutical industries. We supply our customers with GMP and FDA-compliant dry heat sterilisers and vacuum heat and drying cabinets for the most diverse uses.

High-efficiency hot air sterilisation

Dry heat sterilisation offers companies a range of advantages. Since only hot air is used, reliable sterilisation is possible, even at high temperatures. The additional use of chemicals is unnecessary. Depending on the temperature level, the sterilisation process is many times faster than with other methods. This saves time and reduces costs.

Our products and services

- Clean room sterilisers
- Clean room heating and drying cabinets
- Vacuum heating and drying cabinets
- Explosion protected heating and drying cabinets
- GMP-compliant and FDA-compliant
- Qualification/documentation
- Servicing, maintenance, and repairs



Systems and solutions.

Reliably meeting the highest hygiene requirements.



VHS dry heat sterilisers

Our VHS sterilisers, with a nominal temperature of up to 300 °C, are flexible to use and meet the requirements of clean room class ISO 7 in compliance with EN ISO 14644-1. The wide range of standard models permits the sterilisation of small parts and large containers. Depending on size, they are suitable for loading trolleys with grids and permit particularly easy handling.

In addition to our standard products, we manufacture custom units for special requirements and dimensions. One example is our wall-mounted VHSD GMP with pass-through between sterile and non-sterile areas. VHS 4 to 12 are designed to accept sterilisation units (StE standard).



VVT vacuum heating and drying cabinets

Our VVT vacuum heating and drying cabinets permit particularly rapid and gentle drying of powder products and granulates. If need be, evaporated liquids can be recovered. All units are also available in explosion protected versions.



VHSF dry heat sterilisers

Our VHSF dry heat sterilisers, with built-in air circulation filter, meet the requirements of clean room class ISO 5 in compliance with EN ISO 14644-1 throughout the whole sterilisation cycle. The high-performance particulate air (HEPA) filter permits reliable sterilisation and depyrogenation at temperatures up to 300 °C.

VHSF 1-4 dry heat sterilisers, using laminar flow technology with high temperatures (up to 350 °C) are outstanding for reliable depyrogenation. The vertical laminar airflow ensures the particularly uniform temperature distribution in the sterilisation chamber.



Weiss Pharmatechnik markets products from the heat technology branch of the business for the pharmaceutical industry in Germany.

Example application: Recipharm.

Hot air sterilisers for reliable production of medicines.

The German subsidiary of Swedish pharmaceuticals specialist Recipharm is located in Wasserburg. As a subcontracting manufacturer, Recipharm produces products for other pharmaceutical companies. The bottling of sterile solutions for injection is one of the services that it offers.

Highest cleanliness guaranteed

Our sterilisers guarantee maximum safety in every production step. The sterilisers ensure that products used in filling machines can pass through the air locks from clean room class D to clean room class B. The hot air sterilisers kill off germs and sterilise and/or depyrogenate the containers. This is crucial to ensuring that solutions for injection are bottled under sterile conditions. After bottling, some of the containers are freeze-dried, closed, and sent out for delivery.

Many years of partnership at the highest level

In the past years, Vötsch Industrietechnik delivered three hot air sterilisers: VHSFD 100/150 GMP, NTSFD 100/150 GMP, and VHSFD 75/125 GMP. In addition, Recipharm uses three climatic cabinets from Weiss Umwelttechnik. On-time delivery and reliability of the sterilisers were particularly important for these orders. The units had to be exchanged during the two-week holiday closing so as not to interrupt the flow of production. Vötsch delivered punctually with a run-up time of about 16 weeks; production with the new hot air sterilisers was started as planned.

"We decided on vötschtechnik because we had very good experience with the company in the past," comments Josef Schaberl, Deputy Technical Manager at Recipharm Wasserburg. "The vötschtechnik service personnel was also always very experienced and reliable."

Reliably ensuring durability.

Tensile and materials testing under all climatic conditions.

To test whether the packaging of medicines provides sufficient protection, extensive materials testing must be carried out in the pharmaceutical industry. The durability and behaviour of the materials are tested under various climatic conditions.

Guaranteeing product safety

Various environmental factors during production, storage and transport can have a negative influence on the functionality and lifetime of substances, products and packaging. For quality to be guaranteed reliably, tensile tests must therefore be carried out in climatic chambers under precisely predefined climatic conditions.

To obtain approval for a new pharmaceutical product, manufacturers must, furthermore, test extensively all the materials used.

Special solutions for the pharmaceutical industry

Building on our climatic chambers in the ETE and EKE series, we have developed special solutions for the pharmaceutical industry. These solutions can be precisely adapted to the needs of our customers. They are ideally suited to test reliably the quality of pharmaceutical packaging.

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 range ETE and EKE:

E-Type: compact model with machine in the rear area

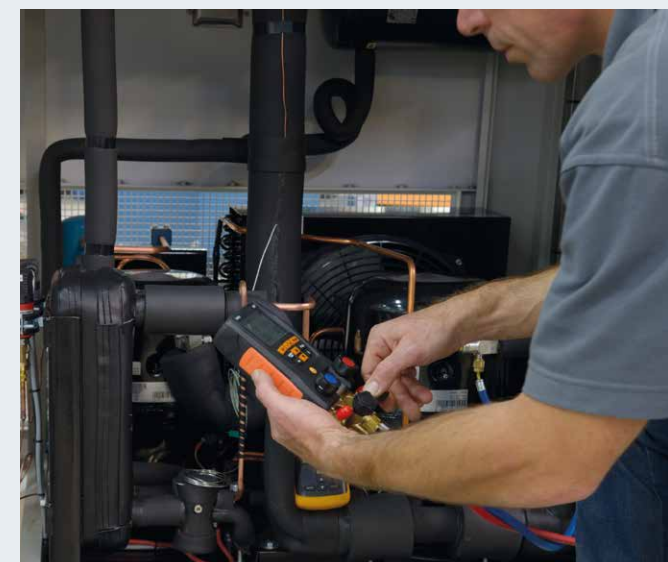
C-Type: versatile chamber on floor rails

M-Type: separate test chamber and machine part 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, maintenance and after-sales services



Creating optimum laboratory conditions.

Plant growth cabinets and rooms for pharmaceutical research.

Genetically modified plants and insects can produce pharmaceutically active substances for medicines. The breeding and cultivation for research purposes places high demands on circadian lighting and climatic conditions, which must be met by a plant or insect breeding system.



Solutions for laboratories

The **weisstechnik®** Fitotron series is a combination of top quality, flexibility, and user-friendliness. Various product ranges are available for applications in the field of pharmaceuticals.

Fitotron SGC 120

Up to 3 m² of illuminated cultivation area on multiple levels for insect rearing, Arabidopsis, tissue cultures, germination, plant rearing and many other possible applications.

Fitotron HGC

Up to 1.5 m² of cultivation area for large plants such as maize, barley, wheat and C4 plants requiring high light intensity.

Fitotron SGR

Plant rearing rooms in various sizes up to 25 m² on several illuminated levels for uses including small plants, Arabidopsis, insects and tissue cultures.

Fitotron CGR

Plant rearing rooms in the sizes 4, 6, 8, 12 and 18 m² with ceiling-mounted, high-intensity lights. Fitotron CGR is designed for large plants such as maize, barley, wheat, and C4 plants. All rooms and chambers are equipped with the latest computer technology. The units are operated from a touch panel, which provides numerous, pre-programmed options. Temperature and humidity can be set just as easily as day and night times, at the press of a button. In addition to these standard ranges, we can supply individually customised solutions.



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.



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.

We are always there for you.
You can reach us by telephone
or by e-mail, 24 hours a day,
7 days a week.



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service@weiss-pharma.com

Clean room technology

For manufacture under clean room conditions, we can issue the legally prescribed, periodic certifications of fault-free operation of the installation. 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 according to the Energy Saving Ordinance (EnEV) 2009. Our energy check meets the legal requirements of EnEV.

Training

We carry out regular service training sessions, free of charge. Furthermore, our experts train our customer's 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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Management
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Because environment and climate are
more to us than just a part of our name.

