



Product overview Weiss Pharmatechnik.

**Industry-competent and
uncompromisingly safe.**

Innovative for Life Sciences.

Everything at its best for research, development, production and quality assurance.



Reliable partner of an innovative industry.

Every day, people in the pharmaceutical industry around the world work to protect and improve the lives of all of us by developing and manufacturing new medicines, optimized medical devices and individual therapies.

Weiss Pharmatechnik supports companies, laboratories and research institutes with comprehensive expertise and profound industry competence to achieve these goals safely and sustainably. Our reliable, innovative products and customized solutions from a single source are sure to meet the high demands of a future industry in transition.

In this way, we support our customers in successfully implementing scientific findings more quickly, making production even safer and further increasing product quality.

Weiss Pharmatechnik offers a versatile and proven range of products and services based on decades of experience, especially for the areas of personal and product protection, clean room, weighing and transferring, sample drawing, hot-air sterilization and stability testing. All solutions meet or even exceed relevant guidelines and standards. Be sure.

Security knows no compromise.

Weiss Pharmatechnik. You can count on us.

Our containment solutions.

Working with active ingredients is a real challenge. Our flexible containment systems in innovative closed and open design guarantee maximum safety with the greatest possible process flexibility thanks to special air-guidance technology. This is how you protect your employees, your products and the environment most effectively.



Our stability testing systems.

Pharmaceuticals are subject to particularly strict guidelines. With our climate simulation systems, you can perform the tests and storage required for stability testing of pharmaceutical products most safely and in accordance with legal requirements - including documentation, qualification and validation. Surely, we also have the optimal solution for you in our program.



Our customer specials.

Benefit from our experience for your individual requirements. Your advantage: one contact for innovative, customized and complete solutions from a single source. Always in reliable compliance with all relevant standards, directives and laws - which you can rely on.



WIBO® Safe Isolators.

Safest technology for maximum safest operation.



The handling of active biotechnological substances in production is highly hazardous and requires a great deal of employee protection, but also product protection. The isolator technology is the safest in pharmaceutical production and is being used more and more frequently.

OEB 4-6

Aseptic Isolator for batch preparation in sterile production, in ATEX-compliant design

- Dispensing and weighing of solids and liquids and transfer to the container underneath
- Protective enclosure of the non-explosion proof analytical balance for ethanol filling in the workroom
- Material lock with integrated endless liner
- Optionally also with WIP*/CIP** system and H₂O₂ decontamination

*WIP = Wash-in-place. **CIP = Clean-in-place.



OEB 4-6

Containment Isolator for handling solid sample material classified according to OEB 4 to 6 in the QC (Quality Control) laboratory

- Negative pressure isolator for personal and room protection with gas-tight and specifically ventilated working chamber
- Material lock and front screen are equipped with an inflatable, circumferential and pressure-monitored seal
- Discharge of sample materials via alpha-beta port endless liner
- Also suitable for weighing and transfer processes
- Optional static seal possible



OEB 4-6

Containment Isolator for safe container loading with active pharmaceutical ingredients (API)

- Negative pressure isolator with material lock for the feeding of predispensed API solids
- Integrated checkweighing station for the filling of API ingredients into the IBC container with filler
- Container docking with customized double flap system
- CIP* system included

Our highlights:

- Customized solutions for laboratory, R&D and production
- Highest safety when handling critical substances up to OEB level 6
- Primary protection type: personal and room protection
- Self-sufficient supply and exhaust air system
- Optional: integration of WIP*/CIP** systems and H₂O₂ decontamination

WIBObarrier® Systems.

Innovative 3-zone principle for reliably stable protection.



The WIBObarrier system was specially developed for work areas where increased personal protection and a high clean air quality are required for product protection. The innovative safety workstations operate according to the 3-zone principle. The outlet nozzle integrated in the front hood area builds up a stable clean air curtain that protects employees, product and the surrounding area. The product remains free from contamination. While HEPA-filtered clean air flows over the product area, the stable barrier curtain protects the user when manipulating dusty and gaseous substances.

OEB 4

Containment System WIBObarrier Vertical Plus for weighing and decanting

- With hydraulic lifting device for the working surface for easier cleaning of the air-guided underside of the work surface
- Has connections for compressed air and nitrogen in the working area
- Works in recirculation system, with HEPA-supply air filters in the hood and F9/H14 exhaust air filter units in the rear wall

Our highlights:

- High personal, environmental and product protection
- Guaranteed cleanliness class 5 according to ISO 14644-1
- Robust retention according to ISPE-SMEPAC
- Customized design, as open system up to closed high containment system in isolator quality
- GMP-compliant, easy to clean



OEB 4

Containment System WIBObarrier Vertical Plus with sliding pane for weighing, transferring as well as sample drawing

- Sliding pane with glove grips provides splash and carry-over protection
- Features an integrated parking space range for large containers with air-guiding swing door
- In the work surface there is a waste discharge with endless liner system
- Recirculation system with HEPA H14 filter in the hood and F9/H14 exhaust air filter units in the rear wall



OEB 5

Containment System WIBObarrier Vertical Plus for the batch preparation

- Material locks and RTP ports with endless liner ensure the safe inward and outward transfer of products
- Pneumatic lifting device underneath the work surface for docking the preparation tank
- The closed front pane with glove ports can be folded up if necessary
- With separated weighing cabin and base cabinets on the right side

WIBOjekt® Systems.

Sophisticated clean air curtain technology for targeted shielding.



Robust retention



The WIBOjekt systems protect employees and rooms from pollutant vapors and dusts that can be released during the work process. The specially shaped and perfectly arranged ejector nozzles, in conjunction with stabilizers, provide a safe clean air curtain that specifically shields the work surface from the environment.

Workbench WIBOjekt as a robust industrial workstation with pollutant extraction - for personal and environmental protection

- The work tables can be customized in terms of dimensions and equipment
- Wash basins, funnels, discharges, weighing stones or perforated plates can be inserted into the work surface
- Sockets, media connections and pump and dosing stations for chemicals can be easily integrated in the work area
- The exhaust air-conducting rear wall can be designed with exhaust air filters



Workbench WIBOjekt as cleaning workstation for laboratory glassware in GMP design

- Features sliding splash guard, continuous liner waste system in countertop, sink with perforated metal cover and hot and cold water faucet as well as pass-through with lift gate
- The technical area, the F9/H14 exhaust air filters and the air-recirculation fan are, due to a low overall height, integrated in the left side

Our highlights:

- Enables safe working with hazardous substances
- Reliable personal and environmental protection due to the stable clean air curtain and the targeted pollutant extraction
- Robust retention in accordance with DIN EN 14175-3
- In industrial standard with and without ATEX protection as well as GMP-compliant executable
- Low noise and economical



Walk-In Free Workstation WIBOjekt for decanting and weighing operations

- Protects employees and space during operations such as filling and decanting, weighing as well as loading and unloading of large product quantities
- As an option, the free-standing workstation can be equipped with exhaust filters in the back wall

Laminar Flow Systems.

Your reliable personal, product and environmental protection.



ISO 5



Laminar Flow Clean Air Workbench FFM for aseptic processes

- Product protection workbench for the integration of a semi-automatic, aseptic filling machine
- HEPA-filtered clean air with vertical, low-turbulence displacement flow
- Stainless steel design in the working area for easy cleaning
- With sockets and laboratory gas extraction fittings in the rear wall



ISO 5



Microbiological Safety Cabinet UVF-S class II in special design for vaccine production

- Customized designed workbench for product, personal and environmental protection
- Serves the integration of laboratory automation
- GMP-compliant and easy to clean
- Features electrical outlets, laboratory gas sampling fittings as well as measuring probe for on-site particle monitoring

Our highlights:

- Meet the requirements of class A according to EU GMP or cleanliness class 5 according to ISO 14644-1
- Reliable product protection and/or personal and environmental protection
- Customized solutions, with vertical or horizontal, low-turbulence displacement flow, depending on requirements



ISO 5-7



Laminar Flow Clean Air Module MVF as superstructure of a preparation station for the inward transfer process of sample material

- Serves to protect the product when removing outer packaging from containers that are fed by a roller conveyor into a clean room
- HEPA-filtered clean air with vertical, low-turbulence displacement flow



ISO 5



Free Workstation WIBObarrier Flow for activities such as decanting, weighing and sample drawing

- Reliable personal and product protection when working with critical substances up to OEB 4 with free accessibility, without strip curtains
- The vertically directed barrier separating curtain at the front reliably shields the working area from the surrounding area
- Reduced, turbulent zone in the front area compared to conventional LF systems
- Guaranteed clean room class ISO 5 according to ISO 14644-1

Solutions for laboratory and biotechnology.

Future-proof, effective and standard-compliant.

In medical, pharmaceutical, genetic engineering and microbiological laboratories, materials are used that require special safety measures – a major challenge, especially for safety laboratories. Our laboratory and system workplaces fulfil the required statutory requirements and standards highly reliable. We offer you extensive services, so you can be on the safe side in the long run.

DIN EN 12469



Microbiological Safety Cabinet KTB-NS class II according to DIN EN 12469

Our microbiological safety workbenches were specially developed for these high demands. They securely protect people and the environment from harmful emissions and products from contamination. In addition, they offer efficient processes and ergonomic working.

- Safe protection for people, product and the environment
- Meets the requirements of class A according to EU GMP Guidelines or ISO 5 according to DIN EN ISO 14644-1
- Designed for safety level S1 and S2/biosafety level BSL 1 and 2
- TÜV-tested safety
- Quiet, ergonomic and highly efficient



ISPE-SMEPAC



Special Laboratory Fume Hood Workstation for handling with active substances and pollutants

In terms of safety workplaces, we once again set standards here: the special airflow principle with reduced exhaust air not only protects the system but also cuts running costs. The integrated extraction and filter technology opens up a much wider range of applications and makes sure that hazardous materials are handled safely. Thanks to numerous options, the special laboratory fume hoods can be customized to meet your specific requirements. Tailored entirely to your requirements.

- Low exhaust air volume of only 250 m³/h due to partial circulating air
- Energy-efficient and ergonomic workplace
- Table extraction and integrated filter technology in the underframe provide efficient protection
- Tested personal and room protection – robust retention according to ISPE-SMEPAC Guideline

Our highlights:

- Innovative air-guidance technology
- Reliable safety technology
- Execution according to standards
- Economical and ergonomical
- Extensive service portfolio

Stability Test Chambers PharmaEvent.

Test technology you can rely on.

With our stability testing systems, you can execute storage to determine the shelf life of pharmaceutical substances highly safely and in accordance with legal requirements - including monitoring, calibration and qualification.

The spectrum ranges from laboratory-scale systems from 34 to 2,000 l up to walk-in stability test chambers from 10 to 300 m³ for optimum long-term testing.

All systems have the necessary documentation capabilities according to FDA 21 CFR Part 11 and EU GMP Annex 11 and comply with ICH Guidelines Q1A and Q1B as well as national and international requirements. These include WHO, FDA and CPMP, among others.

ICH GUIDELINES Q1A/Q1B
FDA 21 CFR PART 11
EU GMP ANNEX 11



Solutions from a single source.

Benefit from our complete package with documentation, qualification and training options. Weiss Technik takes over all necessary services including DAkkS calibration.

Photostability Test Chamber PharmaEvent

- Photostability test in less than 100 hours
- According to ICH Guideline Q1B
- Ideal distribution of light, UV, temperature and humidity
- Homogeneous irradiation due to special light and UV filter systems
- Temperature range +10 to +50 °C (+5 to +50 °C for 250 l)
- Humidity range 20 to 90% RH
- Available in the following sizes: 250 l, 500 l



Stability Test Chamber PharmaEvent

- Stability tests according to ICH Guideline Q1A
- For climatic storage in constant climate or climatic cycles as well as stress tests and transport simulations
- Temperature range +2 to +70 °C
- Humidity range 20 to 90 % RH
- Available in the following sizes: 280 l, 600 l, 1,300 l, 2,000 l



Our highlights:

- Safe stability testing according to ICH Guidelines Q1A or Q1B
- Documentation options according to FDA 21 CFR Part 11 as well as EU GMP Annex 11
- Monitoring and control SIMPAC® with 7" Multi-user Interface WEBSession® and Audit Trail
- Comprehensive services such as maintenance, calibration and qualification

Stability Test Chambers PharmaEvent.

Heat, cold, humidity? No problem.



Walk-In Stability Test Chambers PharmaEvent

Stability test chambers from **weisstechnik** can be qualified and are individually designed for your requirements. The isolating cells can be optimally adapted to the building structure where necessary, as there is no binding to grid dimensions. The preferred height is 2,700 mm, deviations are possible. The test room volumes range from 10 to 1,000 m³.

Our range of services:

- Stability tests according to ICH Guideline Q1A
- Temperature range +20 to +45 °C
- Humidity range 20 to 80% RH
- Test sample protection, tmin./tmax. and protection against excessive humidity
- Qualification documentation according to GAMP
- Alarm system according to GAMP
- GMP-compliant and according to ICH Guideline Q1A
- Lockable test room door with multiple glazed observation window and emergency opening device
- Low-maintenance electronic temperature/humidity sensors

Stability Test Container PharmaEvent

The mobile stability test containers expand the storage capacities of pharmaceutical manufacturers for drug testing in a simple, uncomplicated way and in compliance with all relevant specifications. They reliably meet all GMP requirements and ICH Guideline Q1A for stability testing of active pharmaceutical ingredients and medicinal products and require only a footprint and a suitable power supply (plug&play). The stability test containers PharmaEvent are available with a test space volume of 18 and 47 m³.



Our highlights:

- Stability tests according to ICH Guideline Q1A
- Customized solutions
- Control system SIMPAC and GMP-compliant control panel WEBSeason pharma with Audit Trail
- Software package SIMPATI pharma for documentation according to FDA 21 CFR Part 11 and EU GMP Annex 11
- Comprehensive services such as maintenance, calibration and qualification

Safe. Compliant. PharmaEvent.

Stability testing, easier and safer than ever.

Benefit from our complete package from a single source with documentation, qualification and training options. Weiss Technik takes over all necessary services including DAkkS calibration.

Qualification Documentation

Our qualification documents for stability test cabinets and chambers as well as validation documents for software validations are created on the basis of the risk-based approach according to GAMP.

EU GMP Annex 11 Compliance

The computer-aided scheme, consisting of the system control SIMPAC and the control software SIMPATI pharma, fulfills the requirements of Annex 11 "Computerized Systems" of the EU GMP Guideline according to the manufacturer's declaration. This can be proven by the software validation.

FDA 21 CFR Part 11 Compliance

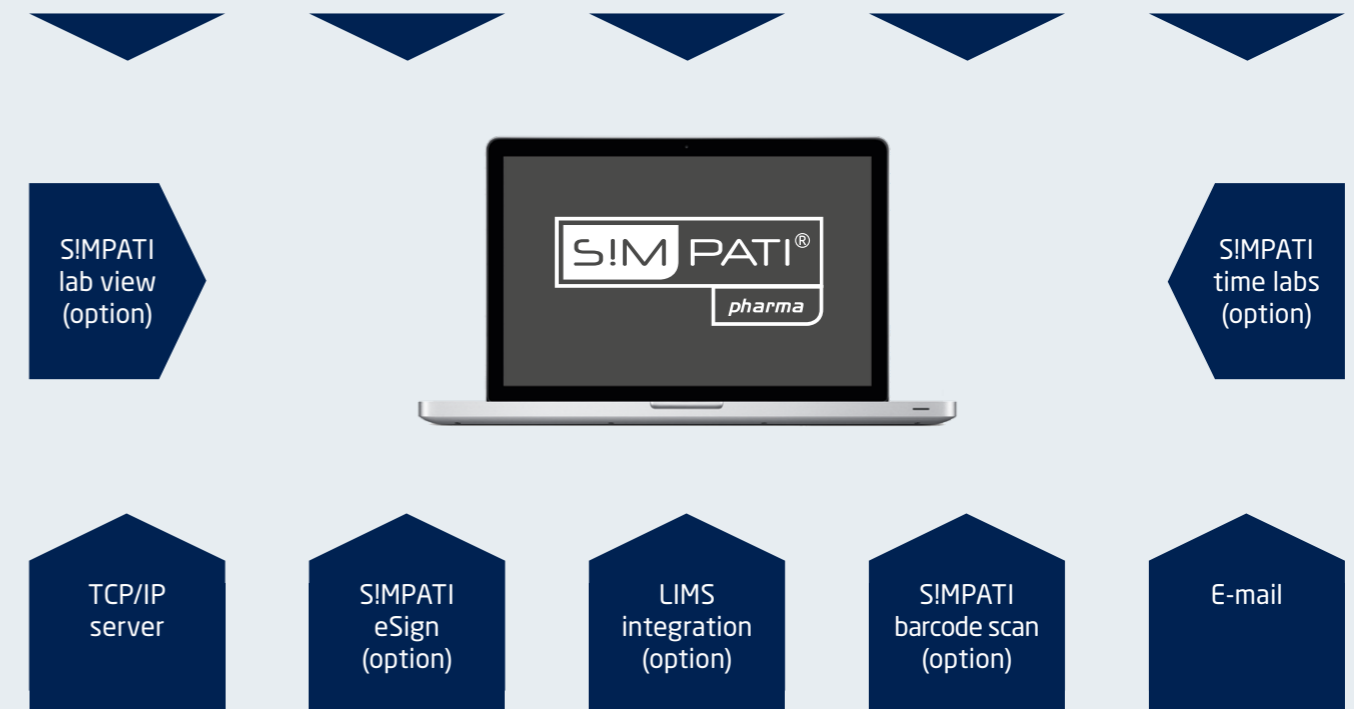
The monitoring software SIMPATI pharma fulfills the requirements of the US American law FDA 21 CFR Part 11 according to manufacturer's declaration regarding electronic recording of data in the pharmaceutical and food industry. This can be proven by the software validation.



Software SIMPATI pharma.

Pretty smart.

Our control and documentation software SIMPATI pharma enables you to efficiently monitor your facilities and systems. In addition, validation documents according to GAMP are provided for the monitoring system.



- Recording of warning and alarm messages (Audit Trail), notification by e-mail if necessary
- Access rights can be set individually for each user
- Tamper-proof storage of all data
- Compliance with FDA 21 CFR Part 11 and EU GMP Annex 11 according to manufacturer's declaration

Customized Containment Systems.

As individual as your requirements.



Transfer and Weighing Workstation WIBObarrier for active substances (API)

- Closed containment solution with lifting device at the rear and integrated IBC container in the underframe
- The product is introduced contamination-free via the WIBO drum port in the rear wall, passes through a sifter, is weighed in the weighing cell and filled into the IBC container via a funnel
- The WIBObarrier is also equipped with a material lock for tools and a waste discharge with endless liner
- Suitable for OEB-5-classified active substances
- Cleanliness class ISO 5 according to ISO 14644-1 even with front panels folded up



Workplace System WIBObarrier Lab Containment with integrated process technology for laboratories

- Thanks to the mobile worktable, several laboratory processes can be implemented with just one WIBObarrier system
- Full process flexibility with low operating and investment costs
- Optionally, the WIBObarrier can be equipped as an open system with a sliding pane or as a closed system with a hinged front pane
- ISO 5 cleanliness class in accordance with ISO 14644-1 even with the front panels folded up

Our highlights:

- Consulting, planning, realization from one source
- Customized solutions
- Optimally matched to the production processes
- Testing of process steps and ergonomics possible by means of mock-up model
- Comprehensive services incl. qualifications and re-qualifications



Transfer Station WIBObarrier for container charging with pharmaceutical products

- Designed for semi-automatic filling of OEB-4/ OEB-5 active ingredients and excipients under high containment conditions
- With material lock, transfer booth and filling booth with integrated powder transfer system
- Container station with double flap system for feeding
- ISO 5 cleanliness class according to ISO 14644-1 even with the front panes folded up

Customized GMP sampling systems.

Your turnkey all-round package from a single source.

Weiss Pharmatechnik offers customized solutions for sample drawing when it comes to increased protection for employees and products. The program ranges from individual clean room workstations with and without housing to complex turnkey clean room systems. This includes all room modules and equipment, including ventilation, control and monitoring technology. The advantage is that the entire process - from planning to qualification - is completely managed by us.

The ergonomic Containment systems WIBObarrier are suitable for GMP-compliant manual sampling. They offer optimum personal and product protection, have a robust retention capacity in accordance with ISPE-SMEPAC Guidelines and achieve cleanliness class ISO 5 in accordance with ISO 14644-1 in the working area.



GMP Sampling System for a disinfection manufacturer

- Solution for the quality control of delivered raw materials in the storage area
- In addition to the sampling cabin with safety workstation, the sampling system also includes a preparation room as well as personnel and material locks

Our highlights:

- Customized solutions for individual containment systems and also complete clean rooms
- Turnkey from a single source - from consulting to qualification
- Optimum personal and product protection during manual sampling
- Pharmaceutical execution



Safety Workstation WIBObarrier Flow for manual sampling in a GMP sampling booth

- Continuous pallet conveyor system with turntables for easy handling of the packs
- Swivelling point extraction for contaminant extraction with solvent-containing sample drawing material
- HEPA-filtered clean air with barrier separating veil in the front area
- Meets the conditions of clean room class ISO 5 according to ISO 14644-1 in the working area with free access



Safety Workstation WIBObarrier Duo for sample drawing in the clean room

- The system is accessible from both sides and allows ergonomic work with several people
- Automatic pallet transfer via the GMP rolling gate of the material lock
- Product exposure <math><1 \mu\text{g}/\text{m}^3</math>
- Meets the conditions of clean room class ISO 5 according to ISO 14644-1 in the working area, even when installed in the gray room

Customized GMP clean rooms.

Full control - better safe than sorry.



Customized Clean Rooms

As a specialist for clean rooms, we offer solutions that are precisely tailored exactly to your facility concept - as energy- and cost-efficient as possible.



Monitoring and GMP Qualification

Clean rooms must be reliably clean - always and everywhere. This is why the qualification of facilities and rooms in pharmaceutical use is a central component of Good Manufacturing Practice (GMP). With our innovative measurement technology, we record, monitor and document all critical parameters.



Personnel and Material Locks

Clean room airlocks ensure the controlled inward and outward transfer of people, materials or products between rooms of different cleanliness classes and different pressure levels. This prevents contamination of the clean area by airborne particles.

Our extras.

Would you like a little more?



Airlock System WIBOclean for people and material

The airlocks are individually tailored to the requirements of the customers. They come in a variety of designs. From ventilated walk-through airlocks to air showers with active cleaning to decontamination airlocks.



WIBO Drum Port for safe and contamination-free docking and undocking of containers

Fiber drums are docked to the drum port using a lift-and-tilt device. A pneumatically inflatable hose seal securely seals the port inlet. Fiber drums and barrel lids are circulated with clean air in a targeted manner.



Chemical Collection Cart for the disposal of acids and alkaline solutions

The mobile collection cart provides safe protection when pumping out toxic waste products. The capacity is up to 100 l. The collection cart is specially designed for our chemical transfer workstations.



Lifting Device, GMP-/FDA-compliant

The lifting columns and lift-tilt-turn devices are matched to our clean air workstations. The stepless lifting and tilting of the containers enables convenient handling during activities such as decanting, filling and weighing. The lifting devices can also be designed to comply with ATEX.

We measure ourselves by our service.

Here for you 365 days a year, 24 hours a day.



For us, service means knowing your requirements and finding sustainable solutions for you. We at Weiss Pharmatechnik fulfill this claim of a true partnership with our services.

Consulting.

Our expert staff is ready to assist you with advice and support. Whether by phone or at your site: take advantage of our know-how.

Maintenance and service.

With regular maintenance of your equipment, you ensure safe, economical operation and extend the service life of your equipment. Our maintenance and service offerings are tailored to your individual needs. An optional maintenance contract from Weiss Pharmatechnik also ensures greater planning reliability and smooth operation.

Spare parts management.

Weiss Pharmatechnik also thinks for you when it comes to spare parts management. We ensure a timely supply of spare and wear parts. In addition, it may be useful to have your own stock on site to a manageable extent. We will be happy to advise you on this.

Retrofit.

We take care of the modernization of your facilities, for example by replacing controls and other components to increase efficiency and optimize energy. We also carry out process adaptations of your devices, such as conversions and extensions up to complete relocation.

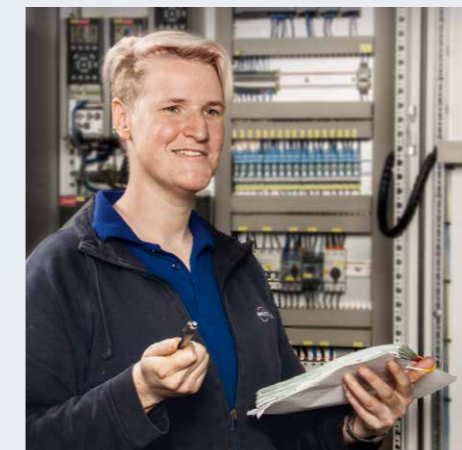
Clean room technology.

Especially for modern manufacturing under clean room conditions, Weiss Pharmatechnik offers the legally regularly required proofs of proper operation. Our specialists can perform all the necessary tasks for you.

Qualifications and re-qualifications.

We offer you all qualifications and re-qualifications that are necessary for the safe operation of your devices. These include FAT, SAT, DQ, IQ and OQ.

You can also find more information on our homepage:
weiss-technik.com/de/service



Our services - lots of good reasons:

- Global service network
- Wide range of preventive maintenance
- Reliable spare part supply
- Quick reaction in case of malfunction
- Proper execution of legally required validation

Our Service Experts are always near you.

24/7-Service-Helpline:
+49 441 57054 110

Passionately innovative.

We work in partnership to support companies in research, development, production and quality assurance. With 22 companies in 15 countries at 40 locations.

weisstechnik

For a safe future.



Environmental Simulation

The first choice for engineers and researchers for innovative, safe environmental simulation facilities. In fast motion, our test systems can simulate all the influences in the world as well as for instance in space. In temperature, climate, corrosion, dust or combined stress tests. With a very high degree of reproducibility and precision.



Air Solutions

As the leading provider of clean rooms, climate technology and air dehumidification, we consistently ensure optimal climatic conditions for people and machines. For industrial production processes, in hospitals, mobile operation tents or in the field of information and telecommunications technology. From project planning to implementation.



Heat Technology

Experienced engineers and designers develop, plan and produce high-quality, reliable heat technology systems for a broad range of applications from heating and drying cabinets to microwave systems and industrial furnaces.



Pharmaceutical Technology

With decades of experience and know-how, we guarantee the most sophisticated clean air and containment solutions. Our comprehensive and innovative range of products includes barrier systems, laminar flow systems, safety workbenches, isolators, airlocks and stability test systems.

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Get Your Pharmaceutical Solution.

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