ZIRBUS TECHNOLOGY

HORIZONTAL FLOOR-STANDING AUTOCLAVES

150 - 1033 LITERS

GERMAN ENGINEERING UNDER HIGH PRESSURE

ZIRBUS TECHNOLOGY GMBH

Since its founding in 1984, ZIRBUS technology GmbH, as a German manufacturer, has gained an outstanding reputation on the international market. We manufacture not only autoclaves but also focus on process technology. A steadily increasing number of customers is putting their trust in Zirbus brand autoclaves and lyophilizers.

Our customers' satisfaction is our top priority...

- **TOGETHER WITH OUR CUSTOMERS, WE CONTINUALLY DEVELOP NEW SOLUTIONS FOR VARIOUS AREAS OF APPLICATION**
- **WE TAKE ADVANTAGE OF EVERY POSSIBLE OPPORTUNITY FOR IMPROVEMENT**
- **PERFECTION IN SERVICE IS WHAT DRIVES US**
- **EFFICIENT AND RELIABLE TECHNOLOGY**
- **A PERFECT COMBINATION OF SOFTWARE AND HARDWARE**

CERTIFIED QUALITY

ASME certified

Module H certified

EN ISO 9001

The quality management (QM) system according to DIN EN ISO 9001 implemented and practiced at ZIRBUS technology GmbH provides the framework for our quality- and cost-oriented activities.

In addition, a risk management system is a component of the QM system.

THE RIGHT EQUIPMENT FOR YOUR NEEDS

ZIRBUS TECHNOLOGY

BASIC LAB

Recommended for the sterilization of simple materials or liquids without removal when dry.

- Integrated steam generator
- SteriTouch control

DRY LAB

Recommended for the sterilization of non-infectious waste bags and materials which require intensive subsequent drying.

- Integrated steam generator
- Vacuum pump set
- SteriTouch control

QUICK LAB · BASIC

Recommended for the sterilization of large quantities of liquids.

- Integrated steam generator
- Rapid water recooling system with air-circulating fan
- SteriTouch control

QUICK LAB

Recommended for the sterilization of non-infectious waste bags, large quantities of liquids and materials which require intensive subsequent drying.

- Integrated steam generator
- Vacuum pump set
- Rapid water recooling system with air-circulating fan
- SteriTouch control

QUICK LAB · ADVANCED

Recommended for the sterilization of non-infectious waste bags, large quantities of liquids and materials which require intensive subsequent drying – this also applies to liquids in closed containers.

- Integrated steam generator
- Vacuum pump set
- Rapid water recooling system with air-circulating fan
- Steam/air mixture method (SAMM)
- SteriTouch control

SAFE LAB

Recommended for operation in the level S2 lab. Recommended for the sterilization of infectious waste bags and materials which require intensive subsequent drying.

- Integrated steam generator
- Vacuum pump set
- Exhaust air filtration EAF
- SteriTouch control

COMPLETE LAB

Fully equipped laboratory autoclave for operation in the level S2 lab. Recommended for the sterilization of infectious waste bags, large quantities of liquids and materials which require intensive subsequent drying.

- Integrated steam generator
- Vacuum pump set
- Exhaust air filtration EAF
- Rapid water recooling system with air-circulating fan
- SteriTouch control

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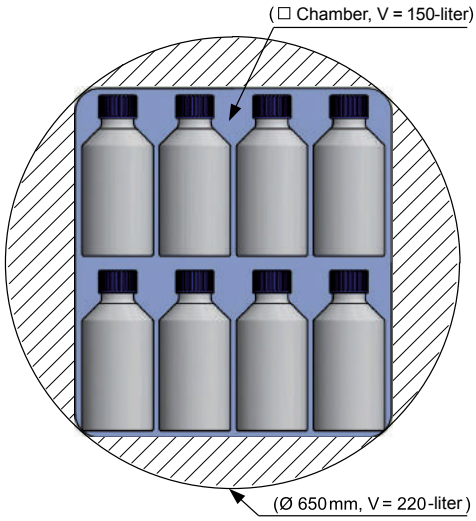
HORIZONTAL FLOOR-STANDING AUTOCLAVES **SERIES 4**
150 - 305 LITER



OPTIMAL USE OF LABORATORY SPACE

The usable volume of an angular chamber can – in contrast to a round chamber – be nearly completely utilized. As a result, the devices have smaller external dimensions.
Loading example:
48 x 1-liter Schott bottles:
☐ = 150-liter chamber capacity
◯ = 220-liter chamber capacity

MADE COMPLETELY OF STAINLESS STEEL

ANGULAR STERILIZATION CHAMBER, CHAMBER CAPACITY = USABLE CAPACITY

COMPACT DESIGN, ONLY 800 MM WIDE

VARIABLE INSERT RACK FOR FLEXIBLE USE

Technical data	HST 4 x 4 x 6	HST 4 x 6 x 6	HST 4 x 6 x 9
Dimensions in mm (W x H x D) 1-door	800 x 1950 x 1100	800 x 1950 x 1100	800 x 1950 x 1400
Pass-through model	980 x 1950 x 1050	980 x 1950 x 1050	980 x 1950 x 1350
Chamber capacity in liters	150	210	305
Free usable space in mm (W x H x D)	450 x 500 x 670	450 x 700 x 670	450 x 700 x 970

Closure system

- The autoclave has a convenient and absolutely secure vertical door, including a fully automatic closure system.
- Safety bar with anti-pinch protection.
- Space-saving: No pivot space is needed in front of the device for the door.
- Low-maintenance door seal.

Transport and batch carts

- Ideal for easy loading and unloading of the chamber.
- Height of shelves can conveniently be adjusted or shelves can be completely removed.
- With docking device and locking mechanism for secure handling.
- Suitable for use in cleanrooms.

RKI*- approved exhaust air filtration with inline condensate sterilization

- For reliable sterilization of items harmful to health (S2/S3 laboratory), the exhaust air is directed via an inline-sterilizable filter.
- Method tested by the RKI and entered in the disinfection list, according to section 18 IfSG [Infection Protection Act].
- Sterile filter gas retention rate: 0.01 µm, mounted in the stainless steel housing, temperature-monitored.
- Floor of the chamber designed as a basin to collect the condensate for inline sterilization.

* Robert-Koch-Institute

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HORIZONTAL FLOOR-STANDING AUTOCLAVES **SERIES 6**
304 - 850 LITER

CAN BE SUPPLIED AS A "PASS-THROUGH MODEL" WITH GASTIGHT PARTITION (BIOSEAL)

ERGONOMIC LOADING HEIGHT OF 800 MM

7-INCH TOUCH SCREEN CONTROL FOR INTUITIVE OPERATION

HEIGHT-ADJUSTABLE TRANSPORT AND LOADING CART FOR EASY LOADING AND UNLOADING

Technical data	6 x 6 x 6	6 x 6 x 9	6 x 6 x 12
Dimensions in mm (W x H x D) 1-door	980 x 1950 x 1100	980 x 1950 x 1400	980 x 1950 x 1700
Pass-through model	1250 x 1950 x 1050	1250 x 1950 x 1350	1250 x 1950 x 1650
Chamber capacity in liters	304	440	577
Free usable space in mm (W x H x D)	650 x 700 x 670	650 x 700 x 970	650 x 700 x 1270

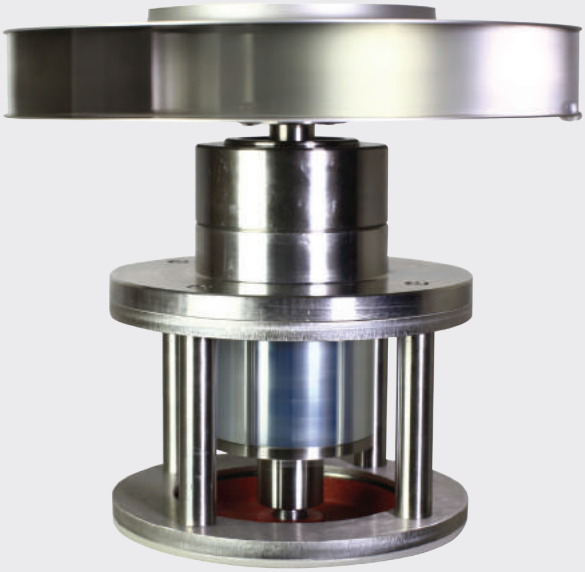
Technical data	6 x 6 x 16	6 x 6 x 18
Dimensions in mm (W x H x D) 1-door	980 x 1950 x 2100	980 x 1950 x 2300
Pass-through model	1250 x 1950 x 2050	1250 x 1950 x 2250
Chamber capacity in liters	758	850
Free usable space in mm (W x H x D)	650 x 700 x 1670	650 x 700 x 1870

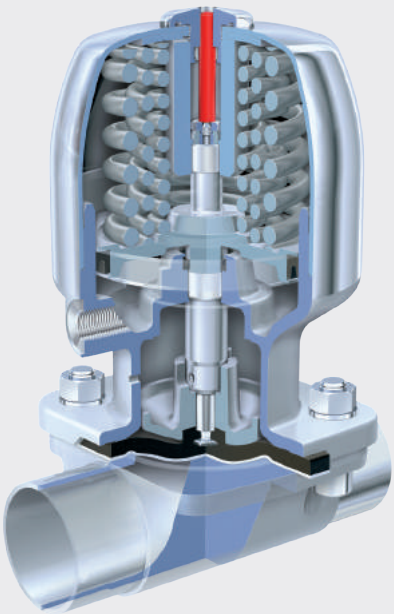
Steam generator

- Compact and high-performance, integrated in the autoclave.
- For avoiding non-condensable gases (NCG) with heated demineralized water tank.
- The water level control is performed by means of a wear-resistant level sensor, independent of conductivity.
- Energy-efficient, optimally insulated.

Air-circulating fan

- For further optimization of the rapid water cooling as well as for shortening the process time.
- Power transmission by means of wear-resistant magnetic coupling.
- For use in the steam/air mixture method (DLGV) → even temperature distribution.
- Does not restrict the usable chamber space.
- Air deflectors for optimal flow and temperature distribution.





GMP design according to DIN 58950

- Dead-space-free design of all pipes and valves connected to the product space.
- Pipes made of material no. 1.4404, pipe class H3.
- Diaphragm valves made of material no. 1.4435, precision casting.
- Interior chamber surfaces sanded and electrochemically polished (Ra < 0.8 µm, optionally Ra 0.4 µm).
- Piping system according to the 3D rule.

ZIRBUS TECHNOLOGY

HORIZONTAL FLOOR-STANDING AUTOCLAVES **SERIES 8**
370 - 1033 LITER

USABLE CHAMBER HEIGHT OF 850 MM, IDEAL FOR FERMENTERS

NARROW WIDTH OF 1300 MM THANKS TO THE VERTICAL DOOR

OPTIMAL RATIO BETWEEN CHAMBER CAPACITY AND FOOTPRINT

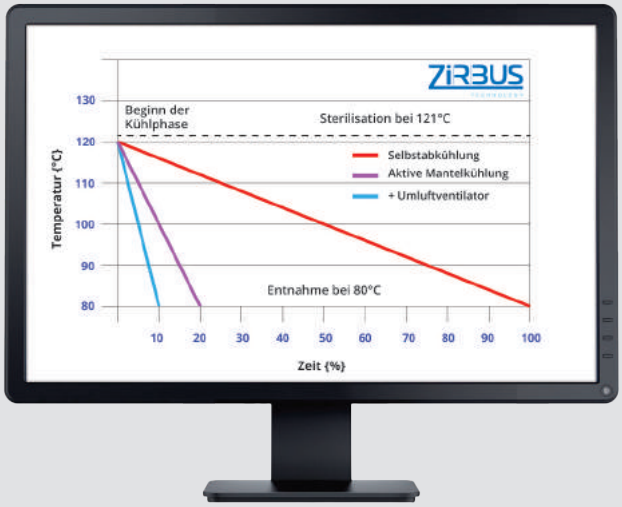
STAINLESS-STEEL PNEUMATIC VALVES AND STEAM PIPES

Technical data	8 x 6 x 6	8 x 6 x 9	8 x 6 x 12
Dimensions in mm (W x H x D) 1-door	1300 x 2300 x 1100	1300 x 2300 x 1400	1300 x 2300 x 1650
Pass-through model	1300 x 2300 x 1050	1300 x 2300 x 1350	1300 x 2300 x 1650
Chamber capacity in liters	370	535	700
Free usable space in mm (W x H x D)	650 x 850 x 670	650 x 850 x 970	650 x 850 x 1270

Technical data	8 x 6 x 16	8 x 6 x 18
Dimensions in mm (W x H x D) 1-door	1300 x 2300 x 1850	1300 x 2300 x 2300
Pass-through model	1300 x 2300 x 2050	1300 x 2300 x 2250
Chamber capacity in liters	812	1033
Free usable space in mm (W x H x D)	650 x 850 x 1470	650 x 850 x 1870

Rapid water recooling

- Shortening of the recooling time by up to 80 % in comparison to self-cooling.
- Ideal for optimal use of the autoclave. Several cycles in the liquid program are possible per day.
- Support pressure regulation via sterile air filter.
- A connection to the in-house cooling circuit for water conservation can be optionally supplied.

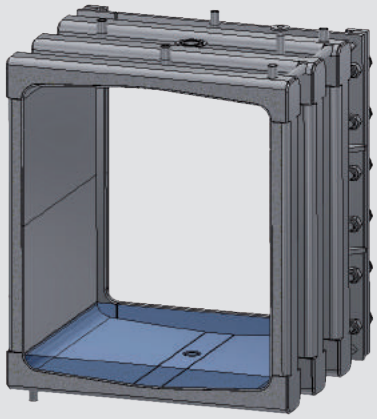


High-performance vacuum pump

- For complete ventilation of the sterile material for a sterilization which can be validated. Steam can reliably penetrate only where there is no residual air. Possible methods:
  · **VOVV:** Single-stage prevacuum, e.g. for liquids and glassware.
  · **FRVV:** Multi-stage prevacuum, e.g. for waste materials in destruction bags.
- Drying in the vacuum is fast and effective, supported by jacket heating.
- A connection to the in-house cooling circuit can be optionally supplied.

Hygiene-design

- For complete emptying, the floor of the chamber is sloped toward the drain.
- The floor of the chamber is designed as a reservoir to collect any condensate present during the waste material sterilization and sterilize it “inline.”
- Rounded corners enable easy cleaning.
- Chamber walls made of high-quality CrNiMo steel, material no. 1.4404 (AISI 316 L); circumferential double mantle made of CrNiMoTi steel, material no. 1.4571 (AISI 316 Ti).



DESCRIPTION OF THE INDIVIDUAL COMPONENTS

CONNECTION TO A CENTRAL STEAM SUPPLY

Alternatively or in addition, the autoclave can be connected to a central steam supply. Design includes all necessary fittings.

GASTIGHT PARTITION (BIOSEAL) FOR PASS-THROUGH VERSION

This (gas)tight partition is required when the autoclave is installed between two rooms with different pressure and safety classes. This ensures that there is no air exchange (diffusion) between the rooms.

WATER-SAVING FEATURE FOR MANTLE COOLING SYSTEM AND VACUUM PUMP

To save cold water, the active cooling and the vacuum pump can be connected to an in-house cooling water circuit. This results in a reduction in water use by up to 95 percent.

STEAM/AIR MIXTURE METHOD (DLGV)

Thermolabile and pressure-sensitive packaging, e.g. blister packaging and closed bottles, can be gently sterilized using this method.

SPRAY COOLING

The sterilization material to be cooled is cooled down very quickly and evenly to the set removal temperature.
Cooling takes place by directly spraying the product with cold water, including support pressure regulation.

HOT WATER IRRIGATION METHOD (HWBV)

Instead of steam, the product is irrigated and sterilized with hot water. This is performed via spray nozzles in the chamber. The method is especially suitable for sterilizing closed containers and large quantities of liquid.

STERILIZABLE INTAKE AIR FILTER

The filter element is mounted in a stainless steel housing and is automatically sterilized inline with each sterilization cycle. An additional Class A PT100 temperature sensor monitors the temperature during this process.
The autoclave display shows the intervals for replacing the filter element.

SPECIAL PROGRAMS

We create customer-specific special programs ourselves through our own software development department. These include, for example:
· ISO - 4802
· ATF filter program
· Durham program

AUTOMATIC FILTER INTEGRITY TEST (WIT TEST)

This test is recommended to ensure increased safety. In addition, it is used to check the function of the supply air or exhaust air filter. The review of the intervals can be defined through the software. This is a validated method.

CONTROL VALVES FOR RAMP FUNCTION

This yields additional adjustment options in the program control:
· Evacuation speed using vacuum pump adjustable in mbar/min
· Heating speed adjustable in °C/min
· Pressure release speed adjustable in mbar/min

The values can be individually adjusted for each program.

VALIDATION

To provide reproducible results, the autoclave processes are individually validated according to DIN EN 17665. The validation is the inspection of the device with regard to its proper functioning. This is performed under real-life conditions with the customer's product in order to check the process parameters.
In doing so, the temperature distribution in the sterilization chamber at various measurement points plays a crucial role. The process requirements are met if the temperature differences are the same as or less than the temperature range specified by the customer.

VALIDATION PROCEDURE

Calibration of the process-related temperature and pressure sensors.

Specification of the program parameters such as sterilization temperature, prevacuum, drying and cooling. In this process, the customer specifies the limiting conditions of the program to be validated.

Performing standardized tests: Example: Bowie+Dick as well as vacuum air test.

To record process data, dataloggers are placed in the sterilization chamber together with the customer's product.

SOLIDS: The datalogger sensors are placed in the product. In the case of closed containers, these are preferably placed in the container.
LIQUIDS: The datalogger sensors are placed in the liquid. Depending on the product, reference containers of the same size – filled with water – may also be used.

Performing the program to be validated.

Evaluation/monitoring of the specified program parameters and limits.

QUALIFICATION

Qualification serves as proof that the manufactured system meets the requirements agreed on and that the performance characteristics as well as the versions are compliant. The qualification is performed according to DIN EN 58950-3 and GMP guidelines.

DESIGN-QUALIFICATION (DQ)

Specification of the requirements for the system in the form of a DQ plan/specifications.
Comparison of the requirements by means of DQ report/specifications, alternative offer (SDS, FDS, HDS).

INSTALLATION QUALIFICATION (IQ)

During the IQ, it is documented that the system, as it is installed, matches the information in the specifications and the requirements from the DQ.
· Material documentation
· Calibration
· Review of the piping plan

OPERATION QUALIFICATION (OQ)

During the OQ, it is documented that the system is fully functional. This includes tests to be performed which are as realistic as possible or which are to be performed under routine manufacturing conditions.

PERFORMANCE QUALIFICATION (PQ)

During PQ, with the customer's product, proof is provided that the system meets the targeted performance parameters under the specified production conditions.

FACTORY ACCEPTANCE TEST (FAT)

Acceptance of the system in the manufacturing factory according to the FAT protocol. Here the proper functioning and design of the system are reviewed together with the customer.

SYSTEM ACCEPTANCE TEST (SAT)

The SAT includes the implementation of the IQ and OQ at the customer's final installation location.
A Zirbus employee qualified to perform this task conducts the qualification of the system on site together with the customer. In this process, he/she verifies the proper functioning according to the requirements specified by the customer.

REQUALIFICATION

During requalification, it is ensured that the system is still in a qualified condition following changes. Quality-related system parameters are assessed and evaluated. In general, the requalification consists of the same tests which were already performed during the initial qualification.

CONFIGURATION SPECIFICATION

The configuration specification has replaced the earlier customary documents of the hardware design specification (HDS) and software design specification (SDS). The following parameters are described here, as a matter of priority:
• Hardware components and versions
• Firmware versions
• Software versions
• Description of the sensors
• Description of the performance parameters
• User profiles

FUNCTIONAL DESIGN SPECIFICATION (FDS)

In the case of the FDS, the system manufacturer confirms the correct execution of the system according to the customer's specifications. The features of the system are described and performance parameters as well as components used are defined and documented.

INDUSTRY PC – IPC
DOCUMENTATION SOFTWARE

The IPC is a add-on module of the standard touch screen. With this add-on, additional comprehensive functions are available to the user. In this way, we achieve the best possible combination of software and hardware for you for controlling and monitoring your processes.

EXPANDED OPTIONS

- Independent documentation (analog values) of temperature and pressure
- Batch documentation as PDF and CSV file
- Automatic printout of batch documentation after the end of the program
- Expandable storage module to file the batch logs
- 99 formulations can be defined as desired
- Integration in the network and thus possible remote maintenance of the entire system
- Optional user management to set up different user groups

The batch documentation consists of a graphic representation of the temperature and pressure gradients. On the second page of the documentation, the individual program steps are listed in table form. If a value should be outside of the target value, this is automatically marked in red. Included in the batch log is also a personalized signature field for acknowledging batches.

DOCUMENTATION

Available in six versions to fit your needs.

BATCH PRINTER

Generates an informative paper printout with all relevant data at the end of the process.

STERILOG

BATCH DOCUMENTATION SOFTWARE

Windows-based software automatically reads the process data from the autoclave and processes these data into a graphic and numeric PDF log (direct coupling with the Ethernet interface RJ45).

USB MEMORY CARD

To record process data on a USB stick at an integrated USB port of the autoclave; includes “SteriLog” evaluation software.

INDEPENDENT DOCUMENTATION

The measured values for temperature and pressure for batch documentation are recorded independently of the SPS control according to DIN EN 285. This enables independent recording of three temperature sensors and a pressure sensor.

10-CHANNEL SCREEN PRINTER

GMP-COMPLIANT

To ensure GMP-compliant documentation, this must be performed according to
FDA 21 CFR Part 11 and GMP.
It must be ensured that the documented process data can in no way be manipulated. The system must be protected from unauthorized access and monitored with the aid of audit trails. Any user activities are documented and recorded. Electronic signatures can be used to confirm formulations.

6-CHANNEL DOT PRINTER

GMP-COMPLIANT

The printer begins recording automatically at the start of the program on the autoclave. All measured values are recorded as a colored curve on scaled folding paper with the values 0 to 150 °C and 100 mm width. The current measured values can be read on an LED display during the recording. In parallel to this, the measured values are saved on an SD card.

SERVICE & QUALIFICATION

SERVICE

We offer you outstanding service. Our employees regularly take part in training sessions to make high-quality service possible.

HOTLINE

Our technical hotline will assist you regarding operation and if you are having system- or process-related problems.
If you need us, we can get to you within 24 hours.

REPLACEMENT PARTS

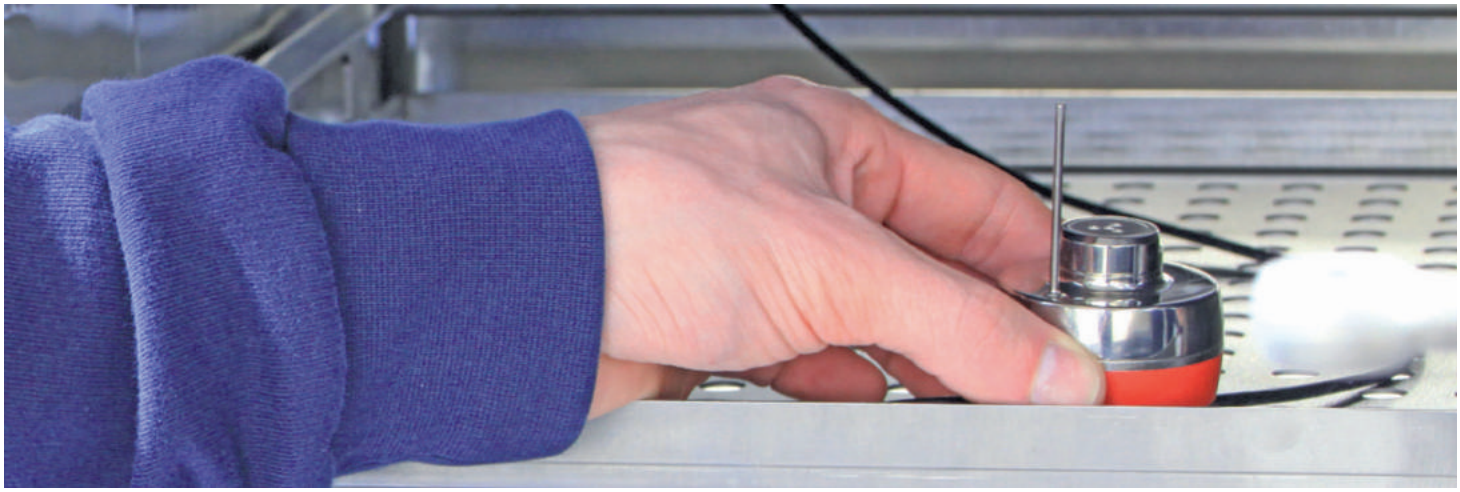
We process spare parts deliveries immediately. Delivery is generally made the following day.

CONSULTATION

We can provide you with advice and draw on our experience to assist you.

OUR SERVICES INCLUDE:

- Delivery, installation and training
- Maintenance and Service
- Calibration with DKD (German Calibration Service)-tested measuring instruments
- Validation according to recognized guidelines
- Qualification DQ / IQ / FDS, SDS, HDS / OQ / PQ according to cGMP guidelines
- Customized process development and optimization
- Sterilization and drying on a contract basis in our own application laboratory



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