




Thermal process technology
Environmental simulation
Project planning

A top-down view of a light blue surface covered with various pharmaceuticals. A large magnifying glass is positioned over the center, focusing on a cluster of pills and capsules. The pills include white round tablets, red and blue capsules, orange capsules, green capsules, and pink capsules. Some capsules are open, showing small white beads inside. The magnifying glass has a black frame and handle.

Whatever you are
going to simulate.

We project it.

Pharmaceutical industry



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You can also benefit from our expertise



► We are WKM

WKM has been active as an independent sales company since 1996. We work as Factory representation and sales partner together with renowned manufacturers. Lachendorf in Lower Saxony became our new headquarters in 2014.

You can reach us for a personal conversation - without an automativ telephone waiting loop! Technical consultation on site is a matter of course for us. We would be pleased to arrange an appointment for a visit to your company or on a virtual meeting. For us, advice does not end with the order. After delivery of the system, you will receive a commissioning and equipment training on request.

You are invited to visit our technical centre to get a detailed impression of our work and the quality characteristics of the product range. Here we can also carry out individual training and further education programmes for you.

WKM offers a comprehensive program to determine all project-specific basics. We implement your requirements precisely and consistently and assist you in all phases of your projects.

Our key to success: **Listen, Advise, Act.**

► References

Abbott Laboratories GmbH	Fresenius Medical Care AG & Co. KGaA	Octapharma Produktionsgesellschaft Deutschland mbH
ABX advanced biochemical compounds GmbH	Gerresheimer Bünde GmbH	PANPHARMA GmbH
Almirall Hermal GmbH	ICHTHYOL-GESELLSCHAFT GmbH & Co. KG	Pharbil Pharma GmbH
Artesan Pharma GmbH & Co. KG	Impfstoffwerk Dessau-Tornau GmbH	Pharma Wernigerode GmbH
Beiersdorf AG	Klosterfrau Healthcare Group	STADAPHARM GmbH
BODE Chemie GmbH	LANXESS Performance Materials GmbH	Strathmann GmbH & Co. KG
BSN medical GmbH	Laverana GmbH & Co. KG	Systema Natura GmbH
Elanco Deutschland GmbH	Lichtenheldt GmbH	Takeda GmbH
ESTEVE Deutschland	LTS Lohmann Therapie-Systeme AG	Trommsdorff GmbH & Co. KG


► Diversity is our strength


Walk-in testing capacities	Constant climate test cabinets	Stability test cabinets
Incubators	Cooled incubators	Temperature test cabinets
Pass-through cabinets	Laboratory refrigerators	Tempering devices
Ex-climate cabinets	Laboratory furnaces	Drying cabinets
Ex-laboratory refrigerators	Peltier cooled incubators	Universal cabinets
Ex-drying cabinets	Clean room drying cabinets	Ultra-freezers
Hot-air sterilisers	Safety drying cabinets	Vacuum drying cabinets
Air-conditioned storage cabinets	Sunlight simulation	Alternating climate cabinets

Climate and stability tests


Air-conditioned storage cabinets

Performance parameters


 Temperature range
+10 °C to +90 °C

 Humidity range
10 % to 98 % relative humidity


Design type



Device properties

 Test room volumes
from 56 l to 2,200 l

Safety





Climate cabinet 400 l with ICH-compliant lighting



Climate storage cabinet 2200 l



Climate storage cabinet 720 l

Constant climate tests / Stability tests

Real time tests with defined climate zones and climate conditions are not only important during the development phase, but also as a test criterion for the preparation of the BGA and the FDA. Based on your results, the minimum shelf life, specifications and storage information can be defined and included for product approval.

The following climate zones are frequently used:

Zone I:	Moderate	21 °C / 45 % RH
Zone II:	Mediterranean, sub-tropical	25 °C / 60 % RH
Zone III:	hot and dry	30 °C / 35 % RH
Zone IVa:	hot and humid	30 °C / 70 % RH
Zone IVb:	hot and very humid	30 °C / 75 % RH

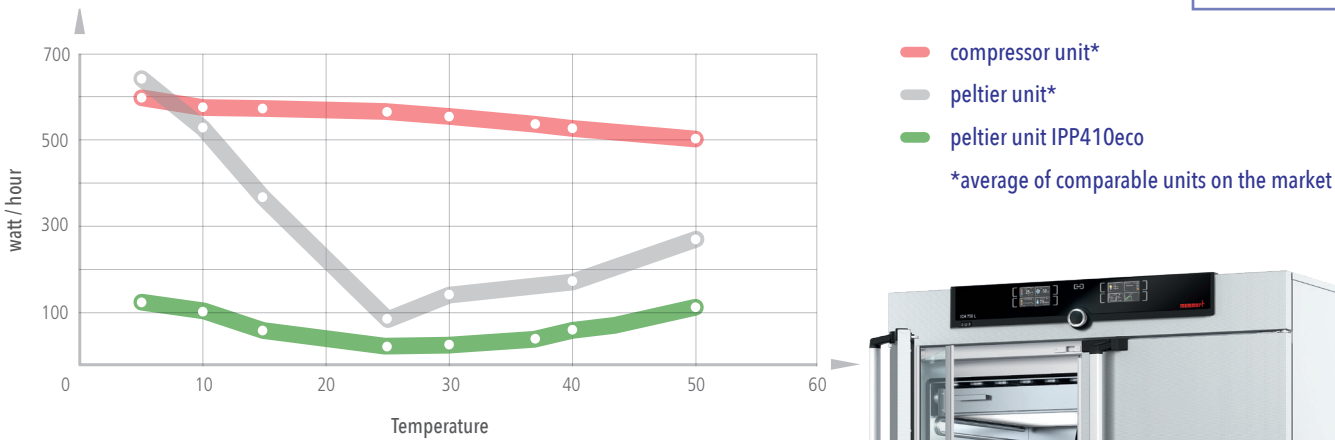
Accelerated tests: 40 °C / 75 % RH

Custom tests, such as swing studies:
2 days at -18 °C followed by 2 days at 25 °C / 60 % RH
2 days at -18 °C followed by 4 days at 40 °C / 75 % RH
2 days at 2-4 °C followed by 2 days at 40 °C / 75 % RH

Photostability tests acc. to CH-Guideline Q1B with compliant UV/VIS lighting.

Operating costs lower through Peltier cooling technology

Find more details here!



Source: Memmert Peltier vs. compressor

For many climate ranges a compressor cooling can be omitted and the energy efficient Peltier cooling used instead. This will significantly lower the operating costs.





Climate storage cabinet 750 l

Climate and stability tests with large test chamber volumes



Walk-in climate storage cells

Performance parameters


 Temperature range
+10 °C to +90 °C

 Humidity range
10 % to 98 % relative humidity


Design type



Device properties

 Test room volumes
from 6 m³ to 230 m³

Safety



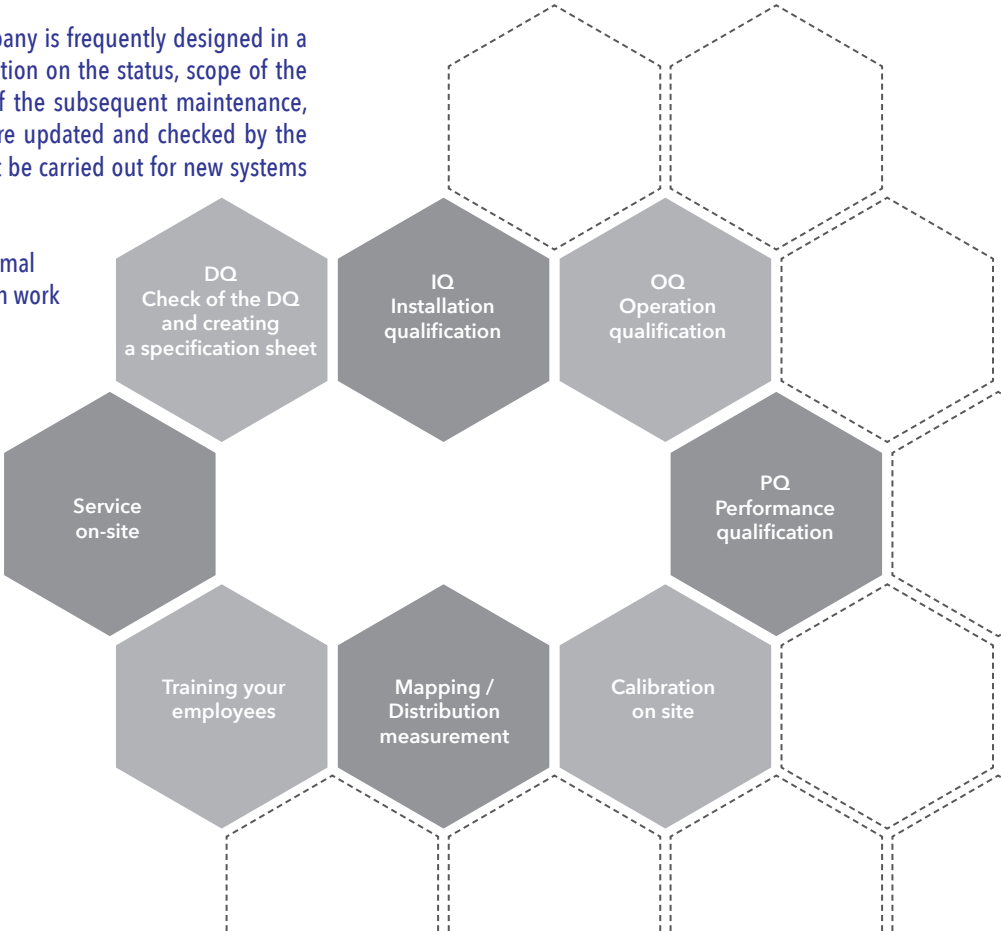


Walk-in chambers

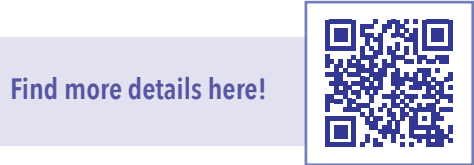
Validation - Basis of your quality assurance

The equipment of a pharmaceutical company is frequently designed in a qualification matrix and contains information on the status, scope of the qualification as well as the scheduling of the subsequent maintenance, calibrations and requalifications. These are updated and checked by the responsible employee. Qualification must be carried out for new systems and equipment.

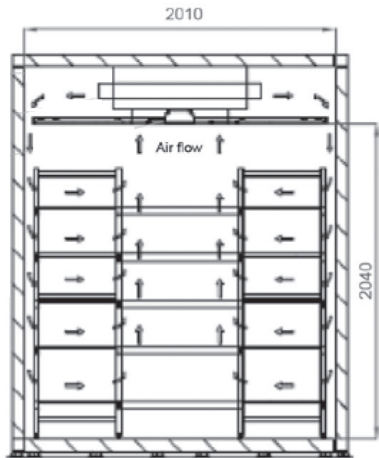
After each qualification stage, there is a formal confirmation that the required qualification work has been properly completed. (see honeycomb diagram)



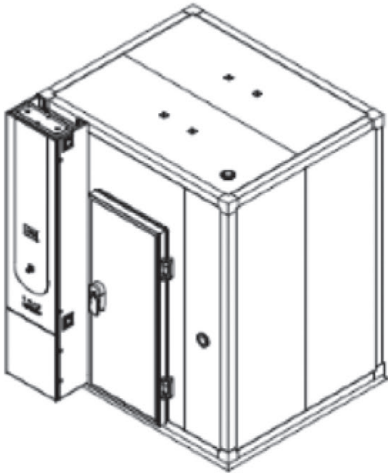
Walk-in chambers in various dimensions



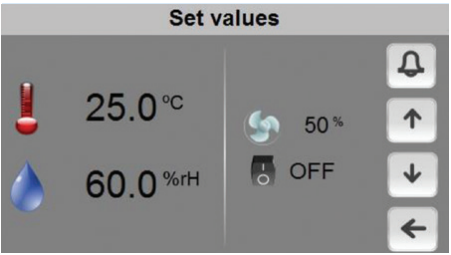
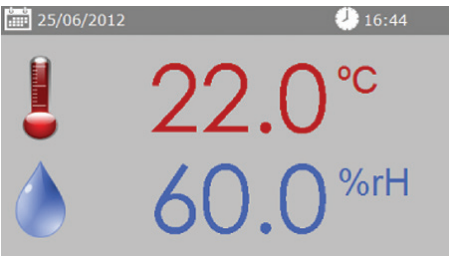
Find more details here!



SECTION A-A



Climaplus Controller control panel



Perfect technology for your safety

Cooling and freezing devices

Performance parameters

Temperature range
-85 °C to +40 °C

Device properties

Test chamber volumes
from 30 l to 1397 l
Accessible cells starting at 6 m³

Design type

Icons: cabinet, chest, and person with lock

Safety

Ex symbol



To securely store sensitive substances we offer a wide selection of cooling and freezing devices. Our laboratory devices ensure excellent temperature stability with their precise electronics and temperature setting accuracy to tenths of a degree. Numerous functions and feature options guarantee that your samples are stored in the best possible manner.



Laboratory refrigerator 340 l

Ultra-freezer, stand-up 700 l



Ultra-freezer, chest 754 l



Precise and reliable

Measuring and recording

Performance parameters

Temperature range
-196 °C to +1300 °C

Humidity range
5 % to 100 % relative humidity

Safety

Ex symbol

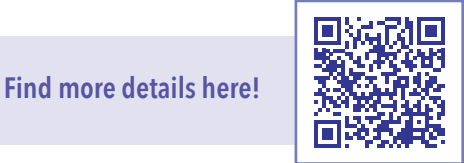
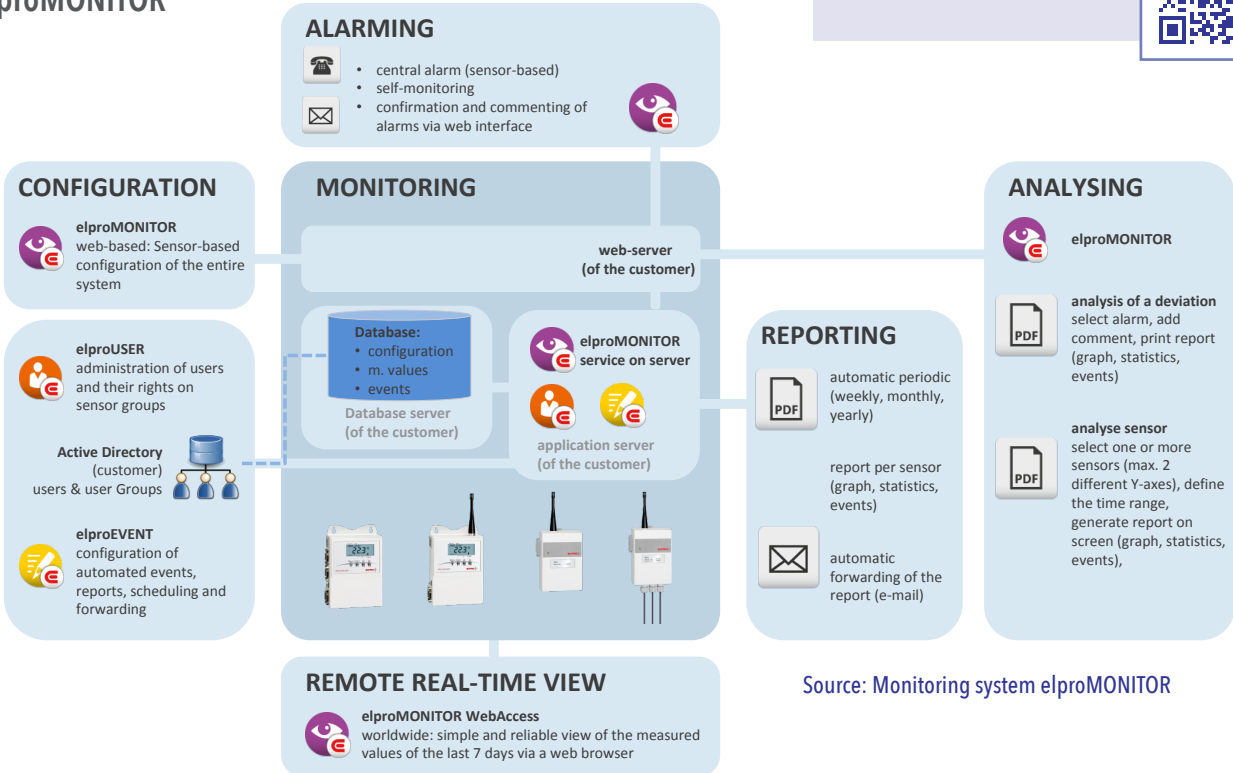


A reliable reproducibility of the test data is an important quality feature. Precise and reliable measurements with data loggers ensures a practical and simple handling of the data backup and analysis. You receive from us a comprehensive product program with the right accessories for your quality assurance, R&D, transport, inventory management and production. Temperature and humidity loggers from our portfolio are precision devices and can be DAkkS calibrated. We cover the requirement ranges from -196°C to +1300°C and 5 % RH to 100 % RH – from cryostats to the muffle furnace. Up to 60 million measurement values in intervals from one second up to several hours can be saved and read out via a computer. Using potential-free alarm outputs, you receive universal solutions, e.g., with the combination with a phone dialler. Especially important for the pharmaceutical industry is the GLP/GMP/FDA 21 CFR 11 compliant software due to its forgery and manipulation protection. Our data loggers are also available with approval for EX - zone I.

Data logging systems



Central monitoring system elproMONITOR



Source: Monitoring system elproMONITOR

WKM Service

Full service

Our internal service team can be reached by phone workdays from 7:00 a.m. to 5:30 p.m. WKM is also your contact person after purchase and commissioning and ensures a proper function of your equipment and system. Our regularly trained service employees are always at your side. We also help without a maintenance contract.



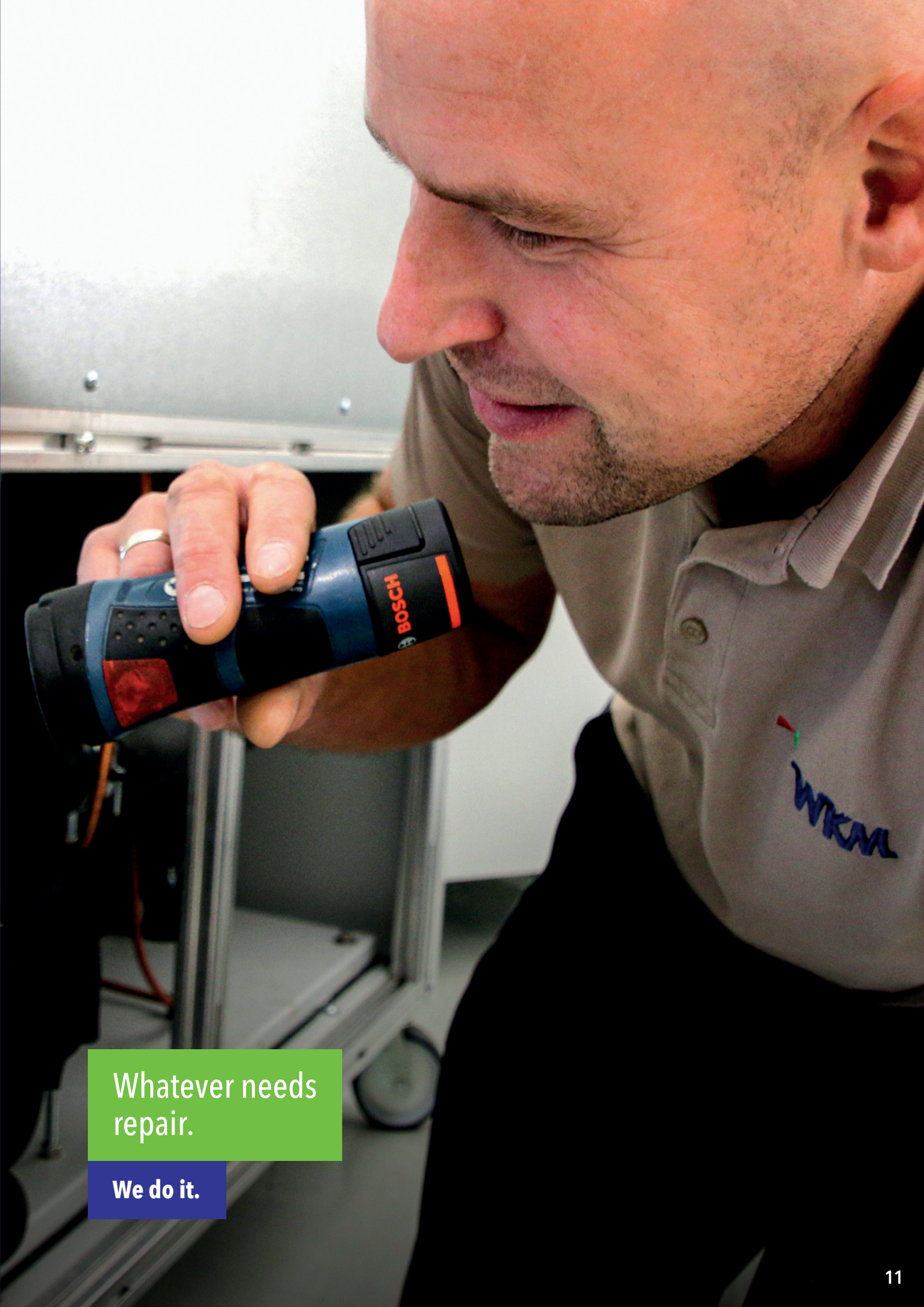
Repair, service, spare part supply

We are pleased to be available for you with our service employees for the following equipment manufacturers:

- Ahlborn GmbH
- Binder GmbH
- caldatrac® Industrieofenbau GmbH & Co. KG
- ELIÖG Industrieofenbau GmbH
- ELPRO Messtechnik GmbH
- Memmert GmbH
- RSI TestSysteme GmbH & Co. KG
- Thermo Electron LED GmbH (previous Heraeus/Kendro)

Our services

- DGUV - V3 measurements (previous BGV-A3)
- Leakage test acc. to F-Gas regulation
- DQ-Design qualification
- IQ-Installation qualification
- Calibration of temperature / humidity
- Leased devices
- OQ-Operation qualification
- PQ-Performance qualification
- Qualification acc. to GMP and FDA specifications
- Spatial distribution measurements (Mapping)
- Repairs
- Maintenance



Whatever needs
repair.
We do it.



WKM

Wärmeprozess- und Klimaprüftechnik Michel GmbH & Co. KG
Im Bulloh 30 - 32
29331 Lachendorf

Phone.: +49 (0) 5145 - 28 666 - 10

Fax: +49 (0) 5145 - 28 666 - 77

E-mail: info@wkm-michel.de

Homepage: www.wkm-michel.de

certified acc. to **DIN EN ISO 9001:2015**

Tisax result available

