

Hilden, October 2024

Quality control of medical products

Leak and flow testing in the manufacturing process

CETA Testsysteme GmbH is a manufacturer of test devices "Made in Germany" and a reliable solution partner in industrial leak and flow testing for over 35 years. With several thousand test devices in use worldwide, CETA helps to ensure quality assurance in the industry. The product range includes leak, volume flow and mass flow testers, digital pressure manometers as well as calibration standards and material for test stations. CETA test devices can detect leak rates down to 10^{-3} mbar*I/s and measure flow rates from 3 ml/min to 200 l/min.

Compressed air, which is available in production facilities worldwide, is used as the test medium. The test methods used are objective, quantitative and can be easily integrated into automated production lines. Compared to testing in a water bath, compressed air testing offers the advantage that the products are not wetted and can therefore be processed, packaged and delivered immediately.



CETA test devices are used for a wide range of medical devices for quality control

Image: CETA Testsysteme GmbH, Hilden

The dynamic viscosity of air ($\eta = 18 \cdot 10^{-6}$ Pa*s) is more than 50 times smaller than that of water ($\eta = 1138 \cdot 10^{-6}$ Pa*s) based on 1013 hPa and 15°C. This means that compressed air is often used for testing for water and media tightness and can be used down to leak rates of 10^{-3} mbar l/s, corresponding to 0.06 cm³/min.

CETA test devices are used for quality control in a wide range of medical products. These include directly fillable products such as pipettes, cannulas, syringes, filter elements, electrical connectors, tube connectors, insulin pumps and valves, as well as encapsulated products such as packaging and sensors. In addition, flow rates through filters, membranes, pipettes and tubes can be measured and the dimensional accuracy of pipes, tubes or channels can be determined. Pressure tests and

functional checks are also possible, such as determining the opening and closing point of pressure-operated valves. Depending on the requirements and the test parameters (test pressure and leak rate), a suitable test device and its technical configuration are selected.

In addition to the test devices, CETA offers a comprehensive service package that includes application consulting, feasibility studies, application support, commissioning, training, online seminars and technical service for CETA test devices.

The CETA calibration laboratory is accredited by the German Accreditation Body (DAkkS) in accordance to DIN EN ISO/IEC 17025 for the measurands pressure, flow rate in gases, leak rate of gases and helium leak rate.

All test devices and calibration standards are supplied with a DAkkS-accredited and internationally recognised calibration certificate at no extra charge. In addition, the test devices are delivered with a 3-year warranty (with annual maintenance), extendable to 5 years.

CETA exhibits at the world's largest medical technology trade fair MEDICA 2024 (11.-14.11.2024) in Düsseldorf (NRW community stand C80, hall 3). At the trade fair, CETA will demonstrate leak testing of an encapsulated product using a table-top fixture and a CETATEST 825 differential pressure leak tester.

In addition, CETA has a lecture on the quality control of medical devices: Leak and Flow Testing of Medical Devices in the Manufacturing Process - as part of the stage program of the community stand.

CETA press release: 538 words / 3,458 characters with spaces

CETA Testsysteme GmbH - Solution partner for industrial leak and flow testing

CETA Testsysteme GmbH, based in Hilden near Düsseldorf, Germany, was founded in 1988 and has been active for more than 35 years as a manufacturer of physical measurement instruments used in leak tests and flow measurements. Compressed air is used as test medium. This testing procedure is characterised by the fact that it can be integrated in the production line with high process reliability.

The test equipment "Made in Germany" is developed in-house and along with the components and accessories (e.g. calibration standards) are manufactured by CETA. This takes into account the high demands on the quality of the internal modules used. A comprehensive range of test devices means that the right solution can be found for almost any testing application.

Semi-automatic test stands are also offered. The test devices are used by customers for quality assurance, quality control and production assurance. The customers are mainly from the automotive industry, medical technology, heating and air conditioning industry, energy sector, fittings and household appliances industry, packaging industry and e-mobility.

The company is certified according to DIN ISO 9001 and won the Quality Award of North Rhine Westphalia in the industry category in 2002. Since 2012, CETA has been consistently certified with a very good credit rating.

The calibration laboratory was accredited in 2004 by the German Calibration Service (DKD) and in 2014 by the German Accreditation Body (DAkkS) - as the successor to the DKD - as a DAkkS-accredited calibration laboratory. The DAkkS-accredited calibration (compliant with the DIN EN ISO/IEC 17025 standard) meets the requirements of the IATF 16949 standard applicable in the automotive industry.

CETA Testsysteme GmbH is the first German manufacturer of leak testers to deliver its test equipment with DKD- or DAkkS-accredited calibration certificate as standard since 2004. From mid-2024, flow testers as well as pressure manometers and calibration standards will also be supplied with a DAkkS-accredited calibration certificate as standard and at no extra cost on initial delivery.

The comprehensive range of services includes consulting, feasibility studies, commissioning, training, maintenance and calibration.

With cooperation partners in China, India, Indonesia, Mexico, Poland, Portugal, Singapore, Thailand, the Czech Republic, Turkey and Hungary and with thousands of test devices in use all over the world, CETA Testsysteme GmbH presents itself as a competent solution partner for industrial leak and flow testing.

CETA profile: 2629 characters with spaces

CETA Testsysteme GmbH
Marie-Curie-Str. 35-37
40721 Hilden, Germany
Tel.: +49 2103 2471-0
E-mail: info@cetatest.com
Internet: www.cetatest.com

Press contact:
Dr Joachim Lapsien
Head of Product Marketing
Tel.: +49 2103 2471-19
joachim.lapsien@cetatest.com