

Hilden, September 2026

MEDICA 2026: Improved product safety through validatable leak and flow testing of medical devices

Risk minimisation through 100%-routine testing during the production process | Qualification & validation | Traceable measurement technology | Use of standardised test methods

Abstract

CETA Testsysteme GmbH, a specialist in industrial leak and flow testing, will present solutions for the quality control of medical devices, assemblies, and components at MEDICA 2026. The non-destructive testing methods, which use compressed air as the test medium, enable 100% routine testing directly within the production process. CETA test devices are used worldwide in automated production lines for quality assurance and enable the reliable detection of even the smallest leaks as well as the verification of functional product characteristics. In this way, CETA supports medical device manufacturers in reliably meeting the high requirements for product safety, process stability, traceability, and regulatory compliance, while sustainably reducing quality-related costs.

Risk minimisation through 100 % routine testing of medical devices

Medical devices must meet the highest quality and safety standards. Even the slightest leaks or deviations in flow rates can impair a product's function and, in the worst-case scenario, affect patient safety. Consequently, an increasing number of manufacturers are turning to automated testing procedures that inspect every single product before dispatch. CETA leak and flow testers enable reliable 100 % routine testing with complete documentation and traceability.

Support during qualification and validation of test processes

In addition to the testing task itself, the areas of qualification and validation of production processes are becoming increasingly important. As an experienced solution partner, CETA provides manufacturers with comprehensive support in the qualification and documentation of their processes throughout the entire DQ, IQ, OQ and PQ chain. The collaboration begins as early as the

initial development phase with feasibility studies and the identification of optimal test methods. In production operations, CETA's test equipment ensures the highest level of process reliability, transparency and traceability through reproducible measurement results and comprehensive documentation.

Testing methods using compressed air as the test medium for a wide range of applications

The non-destructive testing methods used by CETA employ compressed air as the test medium.

The methods are based on standardised non-destructive testing procedures as described in DIN EN 1779 (Criteria for the selection of leak testing methods) and DIN EN 13184 (Pressure change methods).

The CETA range of test devices includes leak testers with differential pressure and gauge pressure sensors, and devices for measuring mass flow and volumetric flow. This makes them suitable for quality testing in a wide range of medical device applications, such as:

- Endoscopes, catheters and tubing systems
- Infusion and transfusion systems
- Filters and filter assemblies
- Ventilation components
- Disposable items
- Drug delivery systems
- Plastic assemblies and medical connection systems



Quality control of pharmaceutical packaging

The 100% leak test is becoming increasingly important for both medical devices and pharmaceutical packaging. As part of Container Closure Integrity Testing (CCIT), CETA leak-test devices enable non-destructive and quantitative testing of packaging systems such as syringes, vials, ampoules, blister packs and pouches. The high-precision measurement methods detect even the smallest leaks and are suitable for automated in-line testing of every single product unit.

The test devices are equipped with industrial interfaces. This enables their integration into higher-level, validated IT systems and supports compliance with FDA 21 CFR Part 11 requirements regarding data integrity, audit trails, user management and electronic data storage. As such, the CETA leak testers make an important contribution to product safety, process reliability and regulatory compliance in accordance with CCIT requirements. The qualification of the employed deterministic test procedures can be aligned with the principles described in USP <1207>. Depending on the application, relevant ASTM standards (like ASTM F2338) may also be considered.

Accredited calibration laboratory | Metrological traceability

An important advantage for customers in regulated sectors is CETA's accredited calibration laboratory for the measurement of pressure and flow in gases (certified to DIN EN ISO/IEC 17025). The calibrations are internationally recognised and ensure the metrological traceability of the test equipment used. The accredited calibration certificate is included as standard. This provides users with the basis for auditable and traceable test processes right from the start of commissioning.

Higher process reliability and lower quality costs

As well as meeting regulatory requirements, automated leak and flow tests also offer significant economic benefits. Faulty products are detected during production, reducing scrap and rework while helping to avoid costly complaints and product recalls. The combination of high-resolution measurement technology, the use of standardised test procedures, accredited calibration, many years of practical experience and a three-year warranty (extendable up to five years) makes CETA's

test equipment a long-term, reliable solution for quality assurance in the medical technology sector.

CETA Testsysteme GmbH – Experience ensures product safety

For more than 35 years, CETA Testsysteme GmbH has been developing test devices for industrial leak and flow testing. Its comprehensive range of services extends from feasibility studies and the development of customer-specific test concepts through to integration into test stations. Thanks to standardised interfaces and easy integration into PLCs and production control systems, CETA test devices make a significant contribution to quality assurance. Several thousand CETA test devices are in use worldwide for quality assurance in production lines.

CETA at MEDICA 2026 | Live demonstration of a leak test application

Visitors to MEDICA 2026 (16–19 November 2026, Düsseldorf) can find out about the latest solutions for leak and flow testing at the CETA stand, as well as discuss specific use cases from the medical technology sector. A particular highlight of CETA's exhibition presence will be a live demonstration of a catheter leak test.

CETA at the MEDICA 2026 trade fair, 16–19 November 2026 in Düsseldorf

Hall 3, Stand C 80 – Community stand for the State of North Rhine-Westphalia

Further information

[CETA Homepage](#)

[Medica 2026](#)

[CETA exhibitor profile at the Medica 2026](#)

[CETA Product Overview](#)

CETA Press text: 6893 characters including spaces

Company profile

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 test devices used in leak tests and flow measurements. Compressed air is used as the test medium. This testing procedure is characterised by the fact that it can be integrated in the production line with high process reliability.

The "Made in Germany" test equipment, together with its components and accessories (e.g. calibration standards), is developed and 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, e-mobility, medical technology, heating and air conditioning industry, energy sector, fittings and household appliances industry, packaging industry, security and defence industry.

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.

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Press Release

CETA Testsysteme GmbH



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