

Hilden, October 2022

Leak and flow testing of medical devices in the production process

The European Medical Device Regulation 2017/745/EU (MDR) came into force on 26 May 2021 after an extended transition period. Among other things, this contains a product reclassification and stricter requirements for manufacturers of medical devices. In addition, the assessment of risks is of particular and higher importance.

It should be noted that all medical devices that are currently approved must be re-certified according to the new regulation.

Many medical devices must function reliably under a wide range of conditions. Media-carrying products (e.g. pipettes, cannulas, catheters, syringes, filter elements, tube connectors, insulin pumps, valves) must be tight against liquid leakage, while for other products tightness against the ingress of liquids or moisture is required (e.g. cameras, endoscopes, sensors, actuators, displays, control elements, packagings). And the correct flow must be ensured reliably and precisely (e.g. for pipes, membranes, filter elements, pipettes, valves).



Figure: Many medical devices have to be tested for leakage or flow during the manufacturing process
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Non-destructive routine testing in the production line (100 % end-of-line testing) is used to monitor and to assure the product quality.

When integrating an inline test procedure into the production process, various aspects must be considered:

- Product features (e.g. expansion during pressurisation, internal structure, settling behaviour of internal components, geometry, adaptation)
- Production process (cycle time, process stability requirements, preceding production process)
- Determination of suitable test parameters (leak test: test pressure and permissible leak rate / flow test: test pressure and flow range)
- Test technology (selection of a test device suitable for the test task)

Finding the right test device for a defined application requires specific expertise and experience. CETA Testsysteme GmbH has more than 30 years of experience in the implementation of industrial testing tasks, combined with its own product development. CETA advises the customer comprehensively - sometimes even during the design phase - in finding the optimum solution.

With a comprehensive range of CETA test equipment (differential pressure and relative pressure leak testers, hydrogen leak testers, mass flow testers, volumetric flow testers), leak rates down to 10^{-6} mbar*l/s and flows up to 220 l/min can be detected. Compressed air, nitrogen or hydrogen (forming gas: 5 % hydrogen, 95 % nitrogen) are used as test media.

The CETA test devices are quality products and are supplied with a warranty of 3 years, with the optional extension to 5 years.

CETA is certified according to DIN ISO 9001 and the calibration laboratory (D-K-19566) is accredited as a DAkkS calibration laboratory (according to DIN EN ISO/IEC 17025) for the measurand pressure (also for on-site calibrations). The CETA leak testers are supplied as standard with DAkkS calibration certificate, which is internationally recognised.

Several thousand CETA test devices are in use in production lines at well-known industrial customers worldwide, many of them also in the testing of medical devices.

CETA will be exhibiting at MEDICA 2022, the world's largest medical trade fair, in Düsseldorf from 14.11. - 17.11.2022 (Hall 3, Booth C80). [Pressemitteilung: 3406 Zeichen mit Leerzeichen](#)

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

CETA Testsysteme GmbH, based in Hilden near Düsseldorf, was founded in 1988 and has been active for more than 30 years as a manufacturer of physical measurement instruments used in leak tests and flow measurements. Compressed air and hydrogen are used as test media. These testing procedures are characterised by the fact that they 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, fittings and household appliances industry, packaging industry and e-mobility.

The company is certified according to DIN ISO 9001 and won the NRW Quality Award in 2002 in the industry category. 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 calibration laboratory. The DAkkS 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 calibration certificate as standard since 2004. Since 2012, CETA has been consistently certified with a very good credit rating.

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

With cooperation partners in China, India, Indonesia, Korea, 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: 2367 characters with spaces

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