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## CETA at the MEDICA: Industrial leak testing and flow measurement



Dear readers,

We are pleased to be exhibiting at the world's largest medical technology trade fair MEDICA 2022 (14.-17.11.2022) in Düsseldorf. You will find us at the NRW community stand C80 in Hall 3, where we will demonstrate leak testing. In addition, CETA will give a lecture on the topic of quality assurance of medical devices on 15.11.2022.

Yours

Günter Groß, Managing Director

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## Medical Device Regulation and new requirements

The European Medical Device Regulation 2017/745/EU (MDR) came into force on 26 May 2021 after an extended transition period. Among other things, it contains a product reclassification and stricter requirements for manufacturers of medical devices. In addition, special and increased importance is attached to the assessment of risks. It should be noted that all medical devices that are currently approved must be re-certified according to the new requirements.

## Requirements for medical devices: Leak tightness and flow

Many medical devices must work reliably under a wide range of conditions

Requirement	Example
Tightness against liquid leakage	Media-carrying products (e.g. pipettes, cannulas, catheters, syringes, tube connectors, insulin pumps, valves)
Tightness against ingress of liquids or moisture	Ensuring the function - Protection of the packaged goods (e.g. cameras, endoscopes, sensors, actuators, displays, control elements, packagings)
Flow	Ensuring the correct flow (e.g. for pipes, membranes, filter elements, pipettes, valves)

## CETA test device program and CETA benefits

Comprehensive test device program: Detection of leak rates down to  $10^{-6}$  mbar\*l/s and flow rates up to 220 l/min.

Test device type	Sensor technology	Test medium	Application
Relative pressure leak tester	Gauge pressure sensor	Compressed air	Pressure gradients from approx. 10 Pa/s
Differential pressure leak tester	Differential pressure sensor	Compressed air	Pressure gradients from 1 Pa/s
Hydrogen leak tester	Hydrogen sensor	Forming gas (5 % H <sub>2</sub> , 95 % N <sub>2</sub> )	Leak rates down to $10^{-6}$ mbar*l/s
Mass flow leak tester	Calorimetric mass flow sensor	Compressed air	Mass flow rates up to 600 Nml/min
Volume flow tester	Laminar flow element	Compressed air	Volume flows up to 220 l/min

### CETA benefits

- More than 30 years of experience in the implementation of industrial testing tasks
- Comprehensive project support
- Several thousand CETA test devices in use worldwide
- Network of international cooperation partners
- High product quality
- 3-year warranty (optionally up to 5 years)
- Common industrial communication interfaces available
- Internationally recognised calibration certificate according to DIN EN ISO/IEC 17025 (standard for leak testers)



### Leak test and flow test in theory and practice at MEDICA 2022

CETA lecture and practical demonstration

Lecture		Practical demonstration	
Topic	Leak and flow testing of medical devices in the manufacturing process	Demonstration	Test station for leak testing
		Test device	Differential pressure leak tester CETATEST 825
Speaker	Dr. Joachim Lapsien, Head of Sales Department	Test part	Encapsulated product
Date	15.11.2022, 3:45 - 4:15 p.m.	Date	14.-17.11.2022, full day
Location	NRW community stand (Hall 3 C80)	Location	CETA booth at the NRW community stand (Hall 3 C80)

### CETA practical tip 1: Integration into the production process

Non-destructive routine testing is used in the production line (100 % end-of-line testing) to monitor product quality. There are various aspects to consider when integrating it into the production process:

Feature	Details / Special characteristics
Product characteristics	Expansion on pressurisation, special features of the internal structure, settling behaviour of internal components, geometry, adaptation
Production process	Cycle time, process stability requirements, preceding production process
Definition of suitable test parameters	Leak test: test pressure and permissible leak rate Flow test: test pressure and permissible flow range
Testing technology	Selection of a test device suitable for the testing task

### CETA practical tip 2: Test pressures and leak rates in leak testing of medical devices

Application	Test pressure	Leak rate
Catheters	0,2 to 3 bar	0,2 to 1 cc/min
Blood bags	0,15 to 3,5 bar	1 to 10 cc/min
Syringes	0,3 to 10 bar	0,2 to 5 cc/min
Medical boxes	-0,1 bar	0,4 cc/min
Endoscopes	0,2 to 0,3 bar	0,01 cc/min
Aerosol products	0,1 to 0,8 bar	1 to 6 cc/min
Plastic products	0,5 to 2,5 bar	1 to 10 cc/min
Dialysis products	0,4 bar	1 cc/min
Flexible pipes	0,1 bar	10 cc/min

1 mbar\*1/s = 60 cc/min