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COMPAMED

18. -21.11.2019
Hall 8a / Booth L25

Special machinery and testing technology for medical products
Leak Test • Flow Test • Calibration • Service • Design • Manufacturing • Prototyping • Assembly

Dear Readers,

after our successful appearance in 2018, CETA and Gaedigk will exhibit together again this year at the COMPAMED 2019 trade fair from 18th - 21th 11. 2019 in Düsseldorf. At booth L25 in hall 8a, solutions for testing, assembly and handling of medical products will be demonstrated in a practical way.
We look forward to your visit.

Yours *Günter Groß*
Managing Director

Contents

CETA and Gaedigk
A strong partnership in special machinery and testing technology for medical devices

When integrating leak or flow testing into the production process, some customers want a solution from a single source, i.e. a production system with integrated testing technology.

CETA Testsysteme GmbH develops and manufactures leak and flow testing devices and has more than 30 years of experience in the realisation of industrial testing projects. Several thousand CETA test devices are already in use worldwide. (www.cetatest.com)

Gaedigk Feinmechanik & Systemtechnik GmbH - as one of the leading companies for automation technology - has a high vertical range of manufacture and more than 20 years of experience in the design and construction of test benches and equipment up to semi and fully automated assembly lines. (www.gaedigk.de)

For more than 10 years, **both companies** have been working together very successfully on projects. During this time, many projects have been realised with well-known customers from a wide variety of industrial sectors.

Leak and flow testing of medical devices - Medical devices are subject to strict quality control

On 25 May 2017, Regulation (EU) 2017/745 of the European Parliament and of the Council concerning medical devices entered into force. With a few exceptions, the Medical Devices Regulation will apply from 26 May 2020, which will also affect the classification of medical devices and the requirements they must meet.

As a result of the intensification of the Medical Devices Directive, the assessment of risks is of particular importance. Many medical devices must meet a large number of requirements and function reliably under a wide variety of conditions. Media-conducting products must be leak-tight against liquid leakage and the flow must be reliably guaranteed. To monitor product quality, routine testing is used in the production line (100 % EOL testing). Depending on the application, CETA leak testers with overpressure or differential pressure sensors are used for leak testing. Available pressure ranges are between -1 and 30 bar. Here the differential pressure test method is frequently used. Hereby the pressure decay due to leakage is measured as a pressure difference against a leak tight internal reference volume.

The minimum detectable leakage rates with this method are in the order of 10^{-3} mbar*l/s. CETA flow testers with different laminar flow elements are used for medical devices whose flow rate is tested. Thus a range from 3 ml/min to 200 l/min can be covered. Very low leakage rates down to 10^{-6} mbar*l/s (corresponds to a hole diameter of approx. 0.1 µm at 1 bar test pressure) can be detected with hydrogen leak testers.

Special machinery for handling, processing and testing of medical devices - A sensitive area of application

FEINMECHANIK & SYSTEMTECHNIK GMBH GAEDIGK

Gaedigk has extensive and specific experience in the implementation of solutions for medical devices.

Gaedigk offers the full range of development, assembly, testing and manufacturing services. In the production environment Gaedigk offers solutions in automation in combination with assembly processes and integrated testing technologies. When designing devices for the assembly, handling or testing of medical devices there are a number of specific aspects to consider. In addition to the implementation of the - usually very detailed and structured - requirement specification, the normative specifications of DIN EN ISO 13485 for medical device manufacturers must also been taken into account.

Additional product-specific standards and guidelines may also be considered. Biocompatible material must be used for the mechanical components that come into contact with the medical device. As a matter of principle, the design ensures that the dead space is as minimal as possible in order to reduce the risk of cross-contamination.

Competence and solutions for medical devices - Projects realised by CETA and Gaedigk

Depending on the type of product and the feature to be tested, different test methods are used which can be covered with CETA test equipment.

Application	Medical devices (selection)
Directly fillable test parts	Pipettes, cannulas, syringes, filter elements, connectors, hose connectors, insulin pumps, valves
Encapsulated test parts	Packaging (pen cannula), sensors, sealed seam inspection
Internal and external tightness	Shut-off valves (Luer-Lock)
Pressure rise	Dialysis valves
Flow test	Filters, membranes, pipettes, pipes
Mass flow test	Large-volume containers (raw materials, concentrates), membranes
Dimensional accuracy	Cross sections of cables and pipes
Pressure test	Load test laser welded seam
Functional check	Opening and closing point of valves

Gaedigk supports the customer in the different phases of the value chain of medical devices

Application	Functions	Medical devices (selection)
Development	Construction, prototyping, master samples	Adapters, bipolar forceps, gynaecological handling devices, hyperthermia devices, surgical instruments
Test benches	Component recognition, testing, OK / NOK marking, storage of test data on IPC and transfer to MES, modular/ exchangeable	Process valves (medicine, clean room), caps
Assembly systems	Detection and positioning, welding / chiselling, testing, label, modular / interchangeable	Membranes (ultrasonic welding), bipolar tongs (disassembly and recycling), shut-off valves (Luer-Lock), filters, valves
Rotary indexing table (fully automatic)	Disconnect and recognize, soldering, positioning, joining, testing, laser marking	Caps (blood analysis)

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