



# QESSE

SOLUTION TO YOUR PACKAGE INTEGRITY ASSURANCE

## CONTAINER CLOSURE INTEGRITY TESTING

- ✓ VIALS
- ✓ AMPOULES
- ✓ PRE-FILLED SYRINGES
- ✓ CARTRIDGES
- ✓ IV BAGS
- ✓ FLEXIBLE PACKAGES





Q E S S E

# CCI 1000 VACUUM DECAY LEAK TESTER

*CCI 1000 is the new, state of the art, vacuum decay based, testing instrument capable to measure on various types of containers made of glass, plastic, metal, flexible composite.*

- ✓ *Ampoules (empty, liquid or dry filled)*
- ✓ *Vials (empty, liquid or dry filled)*
- ✓ *Pre-filled syringes (liquid filled or empty)*
- ✓ *Cartridges*
- ✓ *Pouches and Sachets*
- ✓ *Bottles, filled and sealed*
- ✓ *Bulk containers small size*
- ✓ *Ophthalmic dropper tip*
- ✓ *IV Bags*



- Vacuum decay is the most established and widely used test method for the detection of leaks from small and medium size containers and packages
- It is nondestructive, quantitative i.e. deterministic, fast, it does not require special gas
- Vacuum circuits and electronics conceived with the state of the art construction standard
- High sensitivity (*minimum size of leaks detectable in a defined container*)
- Excellent repeatability of measurements (*day-to-day, shift-to shift, sample to sample*), i.e. the reliability of the test
- Speed of measurement, i.e. productivity

# STANDARD OR CUSTOMIZED SOLUTION FOR CCIT



Vials, Ampoules, Pre-filled syringes, Cartridges, IV Bags, Pouches, Sachets and other package type can be tested. Nondestructive and deterministic.



The rigid or flexible wall test chambers are simply connected to the instrument, interchangeable, quick and without any tool.

## **WE OFFER**

- *Feasibility Studies*
- *Method Development*
- *Validation IQ/OQ/PQ*
- *Certified positive controls (package with a known, intentional defect)*
- *Calibration & Maintenance*
- *Calibrated flowmeter (optional)*
- *Certified built-in orifice for systems suitability (optional)*

## **REGULATORY STANDARDS**

- *ASTM F2338 Standard Test Method for Nondestructive Detection of Leaks in Packages by Vacuum Decay Method*
- *USP <1207> Chapter*
- *ASTM D6653*
- *EU Guidelines to GMP Medicinal Products for Human and Veterinary Use – Annex 1, Manufacturer of Sterile Medicinal Products*
- *PDA Technical Report No. 27 Pharmaceutical Package Integrity*
- *FDA 21 CFR part 11*



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