



# **AMETEK MOCON SOLUTIONS FOR THE HEALTHCARE SECTOR**

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Test the integrity and barrier properties of your packaging to protect product sterility and quality.

# PROTECTING PRODUCT STERILITY AND QUALITY

There are many standards and safety requirements which pharmaceuticals, medical devices, nutraceuticals, and other healthcare products are required to uphold. The packaging you choose for your products must protect them from physical and environmental damage and contamination.

For over 40 years, AMETEK MOCON has developed and manufactured the market-leading permeation and package testing analyzers used for packaging development and quality control in the healthcare sector.

Here is a selection of our offerings for the healthcare sector.

## PACKAGING DEVELOPMENT



### OX-TRAN® and AQUATRAN®

From individual materials to whole-package testing, these instruments evaluate oxygen, water vapor and CO<sub>2</sub> transmission rates with high sensitivity, allowing you to choose the best material for your needs.

- Precise humidity and temperature control
- Test methods meet ISO and ASTM standards
- FDA 21 CFR Part 11 compliant



### Dansensor® Lippke® 5000

Measure package and seal integrity with a variety of test options on rigid, semi-rigid and flexible packaging.

- Burst, leak, creep, bubble and combined test types
- Test methods meet ISO and ASTM standards (F1140, F2054, F2095, F2096)
- PC software option for FDA 21 CFR Part 11 compliance
- Traceable and reliable test results

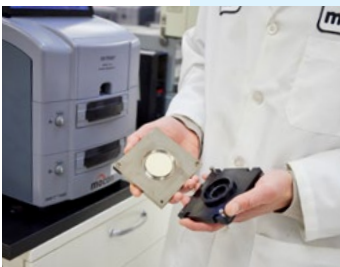
## MEDICAL DEVICE TESTING

Rigorous quality control ensures that medical devices meet regulatory standards, perform as expected, and ultimately support better patient health.



**Quality control testing** is essential for medical devices like IV-bags and catheter bags. These products are often in close contact with the patient and frequently contain sensitive biological materials, so testing their seals, valves and overall integrity is crucial to preventing leakage, infections or adverse reactions.

- Dansensor® Lippke® 5000 tests seal integrity of medical devices with custom accessories, like tube and IV-bag adaptors
- AQUATRAN® 3/34 tests water vapor transmission of materials and whole medical devices



**Permeation testing** is used to test the 'breathability' of medical devices like contact lenses, face masks and surgical gowns. For contact lenses, it is important that sufficient oxygen is able to pass through them to the cornea to prevent complications such as dryness, irritation, swelling or even long-term eye damage.

- OX-TRAN® 2/22 tests oxygen transmission of medical devices using specialized cartridges customized for each application



## PACKAGING QUALITY CONTROL



### Dansensor® Lippke® VC1400

This vacuum leak detection system is designed to automate visual leak tests on flexible, rigid and semi-rigid packaging.

- Dye penetration and bubble immersion test types
- Test methods meet ASTM (D3078) and Farmacopea Mexicana HERMETIC Method IV standards
- Traceable and reproducible test results
- Intuitive interface and secure login options



### Dansensor® CheckMate 4

Quickly and accurately test the residual oxygen levels in sealed modified atmosphere packages (MAP). CheckMate 4 SV (small volume) can reliably test packages with minimal headspace, like vials, ampoules and blister packs.

- Quality control of headspace gas protects product shelf life and efficacy
- Highly accurate, traceable and reproducible test results
- Intuitive interface and secure login options

# PROTECTING EMPLOYEES & PATIENTS



## STERILE ENVIRONMENT MONITORING



### BASELINE® 9100

This gas chromatograph monitors the air for a multitude of compounds, including dangerous emissions from commercial sterilizers, like ethylene oxide, which are commonly used to sterilize medical equipment.

- Monitor air quality to protect employees
- Intuitive interface and flexible multi-sensor set-up
- Highly sensitive sensors, even in trace amounts of less than one part per billion
- Alarm and automatic shut-off functions

## STERILITY AND PACKAGING INTEGRITY

Medical device and pharmaceutical packaging integrity is crucial for maintaining sterility and ensuring patient safety. Properly sealed packaging acts as a barrier against contaminants such as bacteria, moisture, and particulate matter, which can compromise the sterility of the product.

If the integrity of the packaging is compromised, the device or medicine inside may become contaminated, leading to infections or other serious health risks. Packaging also protects products during storage and transportation, preserving their effectiveness.

Regular testing for packaging integrity ensures that sterility is maintained from manufacturing through to the end user, safeguarding both the product's quality and patient well-being.

