

AGLTS

THE AUTOMATIC GLOVE LEAK
TESTING SYSTEM



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IT'S ADVANCED. IT'S AUTOMATIC.
IT'S ABOVE EVERYTHING YOU HAVE USED SO FAR.

A SMART GUARDIAN FOR YOUR BARRIER ISOLATION TECHNOLOGY

The most advanced GMP compliant glove integrity system for isolators and RABs in the pharmaceutical industry, developed in compliance with the international standard ISO 14644-7 Annex E5.



EASY

A user-friendly interface allows the operator to run the testing unit through basic and intuitive commands.
Real time system status can be checked at all times by a supervisor.



AUTONOMOUS

AGLTS requires no external compressed air piping or power supply cables: all the essential pneumatic equipment and a durable Lithium battery are integrated into the testing device.



CUSTOMIZABLE

The custom-designed glove port adaptor allows AGLTS to fit every kind of glove ports. Including yours!



MODULAR

From few to numerous gloves to be tested, AGLTS has it all. Integrated configurations of AGLTS can be upgraded to any number of testing units for a faster parallel performance.
Each glove is recognized by means of Radio Frequency Identification (RFID) Technology for a smart and easy glove management.



PERFORMING

Fast and efficient, AGLTS detects holes down to 100 µm diameter in less than 8 minutes.



WIRELESS

Data can be sent to a supervisor via TCP/IP-based wireless transmission protocol.



DATA MANAGEMENT

A supervisor PC equipped with a dedicated iFix / Historian Data Management Software (DMS) from GE Digital is available for storage and report of the transmitted data.
Implementation on customer's Virtual machine is also possible as option, upon specific customer request.



TEMA SINERGIE
High tech, high care

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KEY FEATURES

- Manufacturing materials resistant to sanitizing agents and bio-decontamination processes
- Automatic complete testing procedures
- Parametric testing formulas
- Integrated pneumatic circuit
- Complete encrypted data/reports storage and download via SD card
- Testing time within 8 minutes, depending on both glove material and dimension
- Standard ergonomic docking station made of SS304 (configurations for 4, 5, 6 and 8 testing units available)
- Custom designed docking station made of SS304 available upon specific request
- Low start-up costs

BENEFITS

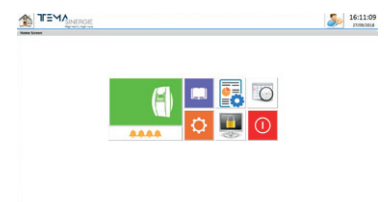
- Saving production time in isolated filling lines, stand-alone isolator systems, and RABS Technology
- Avoiding operator mistakes
- Detecting small holes in the gloves ($\geq 100 \mu\text{m}$)
- Data consulting can be done outside the classified environment

AUTOMATION

- Supervisor based on iFix with Historian Data Management Software (DMS) from GE Digital available upon specific request
- Software development according to Good Automated Manufacturing Practice (GAMP 5)
- 21 CFR part 11 compliant
- Operator friendly interface available in different languages
- VPN connection for remote access and assistance, updates and maintenance available

DOCUMENTATION & VALIDATION

- Complete documentation package according to Tema Sinergie's standards
- Complete validation package, Factory Acceptance Test (FAT), and Site Acceptance Test (SAT)
- Installation Qualification/Operational Qualification (IQ/OQ) protocols and execution
- Performance Qualification (PQ) protocols and execution upon request



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The company Tema Sinergie S.p.A. has a Quality Management System certified by Kiwa Cermet Italia S.p.A. according to the ISO9001:2015 (since 2000) and ISO13485:2016 (since 2013) regulations.