

# AP-IS

ASEPTIC PROCESSING ISOLATOR SYSTEM  
IT'S TIME TO UPGRADE YOUR PROCESSES



# AP-IS

## ASEPTIC PROCESSING ISOLATOR SYSTEM

GUARANTEED ASEPSIS  
MODULAR BASED CONFIGURATION  
AUTOMATIC LEAK TEST  
EASE OF MAINTENANCE  
ERGONOMIC DESIGN  
GLOVE INTEGRITY TESTING  
DATA MANAGEMENT  
ENERGY SAVING



### GUARANTEED ASEPSIS

The AP-IS assures the highest air quality of the isolated environment thanks to:

- an engineered filtration system composed of High-Efficiency Particulate Air (HEPA H14) inlet, unidirectional down flow, return, and exhaust filters
- HYPER, Tema Sinergie's integrated Vapour Phase Hydrogen Peroxide (VPHP) bio-decontamination system for very fast bio-decon cycle (Rapid Gas Chamber complete cycle in 20 minutes, full aeration included)
- inflatable seals made of FDA-approved White Silicon Bio-Guardian®, with anti bacteria inhibitors.



### MODULAR BASED CONFIGURATION

The system is based on a versatile modular concept: the base isolator configuration is composed of a single 4-gloves working chamber which can be easily expanded with additional chambers/airlocks.

This makes AP-IS perfectly suitable to every need and process.  
A select number of available options may be added at a future date.



### AUTOMATIC LEAK TEST

The AP-IS is equipped with a routine automatic leak testing system which performs an independent leak test cycle for each chamber according to the pressure change method (5.2) ISO 10648-2(E).



### EASE OF MAINTENANCE

An integrated sliding control module made of AISI 316L stainless steel, containing electrical and pneumatic components, allows direct access for all maintenance operations.  
A Virtual Private Network (VPN) connection allows a secure and private communication via Internet network and provides remote access and assistance, updates and maintenance any time, everywhere.



### ERGONOMIC DESIGN

Maximizing operators' effectiveness is essential to minimize the risks of accidents, eliminate unscheduled downtime and boost production quality.  
Operators are assured the most comfortable working conditions by the outstanding ergonomics of the AP-IS.



### GLOVE INTEGRITY TESTING

The AP-IS can be equipped with an integrated Automatic Glove Leak Testing System (AGLTS) which performs an independent leak test cycle for each glove mounted on the isolator system according to the Positive Pressure Decay Method described in the international standard ISO 14644-7 Annex E.5.

Wireless Wi-Fi data transmission based on a TCP/IP protocol. Recognition of the glove to be tested by means of Radio Frequency Identification (RFID) Technology. Detection of holes down to 100µm diameter.

## THE SHORTEST WAY TO A STERILE WORLD.

The AP-IS is a cGMP Class A/ISO 5 isolator system specifically designed for R&D, batch scale pharmaceutical production and pharmacies.  
It's a flexible equipment that guarantees the best working conditions in different applications such as Aseptic Filling, Aseptic Dispensing & Sampling and Aseptic Product Transfer.



### DATA MANAGEMENT

The AP-IS can also be upgraded with an Integrated Supervisory Control And Data Acquisition (SCADA) - iFIX with Historian Data Management Software (DMS) from GE Digital.  
DataWall, a software application developed by Tema Sinergie for data management, is also available upon request.



### ENERGY SAVING

Thanks to the new sustainable low voltage ventilation fans, the isolator has a very low energy consumption throughout its life



**TEMA SINERGIE**  
High tech, high care

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## ASEPTIC PROCESSING ISOLATOR SYSTEM

### KEY FEATURES

- Fully PLC controlled isolator system
- Modular configuration concept of the system
- Integrated VPHP generator (HYPER) and distribution circuit
- VPHP resistant anemometer
- VPHP resistant relative humidity and temperature (rH%+T) sensor
- Integrated Sliding Control Cabinet made of AISI 316L stainless steel
- View/Access panel latches with integrated safety switches
- LED lighting system

### GENERAL CHARACTERISTICS

- Main shell structure made of high-grade AISI 316L stainless steel
- Sheathings and support structure made of AISI 316L stainless steel
- Mirror Brite internal finishing (<math><0,3 \mu\text{m}</math>), and Scotch Brite external finishing (<math><0,8 \mu\text{m}</math>)
- Weldings ground, smoothed and polished

### AUTOMATION

- Integrated SCADA – iFIX with Historian DMS available upon customer request as option
- Tema Sinergie Data Management System (DataWall) available upon customer request as option
- SIMATIC IPC277E (Nanopanel PC), 7" Touch Panel with TFT colour widescreen display
- PLC Siemens S7-1500
- 21 CFR part 11 compliant
- GAMP compliant software development
- VPN connection for a secure and private communication via Internet network – remote access and assistance, updates, maintenance and training
- UPS for PLC reliability

### OPTIONAL INTEGRATED EQUIPMENT

- VPHP sensor for TLV environment (safety sensor)
- VPHP sensors for chamber(s) concentration monitoring
- External Catalytic Unit for H<sub>2</sub>O<sub>2</sub> break down
- Rapid Transfer Port (RTP) and transfer container
- Integrated Viable & Non-viable (Particle) monitoring system
- Integrated Automatic Glove Leak Testing System (AGLTS)
- Integrated 21 CFR part 11 compliant paperless graphic recorder
- Uninterruptable power supply (UPS)

### DOCUMENTATION & VALIDATION

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



REV. 01\_20



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.