

# HC-IS

**HIGH CONTAINMENT ISOLATOR SYSTEM**  
CONFINE THE PROCESS, NOT YOURSELF!



# HC-IS

HIGH CONTAINMENT  
ISOLATOR SYSTEM

MAXIMUM SAFETY.  
MODULAR BASED CONFIGURATION  
AUTOMATIC LEAK TEST  
GLOVE INTEGRITY TESTING  
INTEGRATED WASH-IN-PLACE (WIP)  
EASE OF MAINTENANCE  
DATA MANAGEMENT  
ENERGY SAVING



## MAXIMUM SAFETY

Maximizing operator protection is the primary characteristic of a HPAPI containment isolator. Tema Sinergie HC-IS assures very stringent HPAPI containment levels ( $\leq 5 \text{ ng/m}^3$ ) thanks to a perfect combination of design and manufacturing strategies. The system is equipped with inflatable and/or static seals made of FDA approved EPDM (Ethylene Propylene Diene Monomer) to guarantee air tightness Class II (ISO 10648:2). The HC-IS is therefore the perfect adaptable solution for different applications, such as Product Transfer, Manual Sampling, Weighing and Dispensing operations of High Potent Active Pharmaceutical Ingredients (HPAPI).



## MODULAR BASED CONFIGURATION

The system is based on a versatile modular concept: the base isolator configuration is composed of a single working chamber which can be easily expanded with additional chambers and/or airlocks. This makes HC-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 HC-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).



## GLOVE INTEGRITY TESTING

The HC-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.



## INTEGRATED WASH-IN-PLACE (WIP)

The system is provided with Integrated manual Wash-In-Place (WIP) for cleaning processes, thus improving safety for the operators involved in the production of potentially hazardous compounds and reducing the risk of possible cross contamination. Automatic solutions available upon customer request as an option.



## EASE OF MAINTENANCE

An integrated compact sliding control module made of AISI 316L stainless steel, containing electrical and pneumatic components, allows direct access for all maintenance operations. An external monolithic sliding cabinet made of stainless steel AISI 316L is also available alternatively. 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.

## WHEN THE HIGHEST OPERATOR PROTECTION IS REQUIRED.

The High Containment Isolator System (HC-IS) is a GMP Class 2 modular containment enclosure designed for the most challenging containment levels during manipulations of potentially hazardous compounds for Research & Development, Production and QC. Fully custom-designed solutions (HC-IS Series) available according to User Requirements Specification (URS).



## DATA MANAGEMENT

The HC-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



# HC-IS

## HIGH CONTAINMENT ISOLATOR SYSTEM

### KEY FEATURES

- Modular based configuration of the system
- Fully PLC controlled isolator system
- Integrated Wash-In-Place (WIP)
- Handles with integrated safety switch
- LED lighting system
- Integrated compact control module

### GENERAL CHARACTERISTICS

- Main shell structure made of 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 an option
- Tema Sinergie Data Management System (DataWall) available upon customer request as an option
- SIMATIC IPC277E (Nanopanel PC), 7" Touch Panel with TFT colour widescreen display
- PLC Siemens S7 series
- 21 CFR part 11 compliant
- GAMP 5 compliant software development
- VPN connection for a secure and private communication via Internet network - remote access and assistance, updates, maintenance and training

### OPTIONAL EQUIPMENT

- Rapid transfer port (RTP), and transfer container
- Integrated weighing scale & operator panel
- High Containment Split Butterfly Valve (HCSBV)
- Fully automatic Clean-In-Place (CIP)
- Continuous liner, and welder
- Integrated inert gas distribution and monitoring system
- rH%+T sensor
- Vacuum dryer
- Vacuum cleaner
- Integrated Automatic Glove Leak Testing System (AGLTS)
- Integrated 21 CFR part 11 compliant FDA 21 CFR Part 11 paperless recorder

### DOCUMENTATION & VALIDATION

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