

# CLF-IS

COMPACT LAMINAR FLOW ISOLATOR SYSTEM  
SMALL SCALE, FULL COMPLIANCE



**TEMA** SINERGIE  
High tech, high care

# CLF-IS

## COMPACT LAMINAR FLOW ISOLATOR SYSTEM

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



### GUARANTEED ASEPSIS

The CLF-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 (optional)



### MODULAR BASED CONFIGURATION

The system is based on a versatile modular concept: the base isolator configuration is composed of a single 2 to 4-gloves working chamber which can be easily expanded with additional chambers/airlocks. This makes CLF-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 CLF-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

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 CLF-IS.



### GLOVE INTEGRITY TESTING

The CLF-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.



### MAXIMUM SAFETY

The Compact Laminar Flow Isolator System assures very stringent containment levels along with a full aseptic environment thanks to a perfect combination of design and manufacturing strategies. The system is equipped with inflatable and static seals made of FDA-approved silicon compound, to guarantee air tightness Class II (ISO 10648:2). The CLF-IS is therefore the perfect solution to perform antiblastic compounding and chemotherapeutic manipulation.

## THE PERFECT ALLY FOR YOUR HOSPITAL PHARMACY

The Compact Laminar Flow Isolator System is a modular cGMP Class A/ISO 5 isolator system specifically designed for safe handling of hazardous compounds (Chemotherapy, Oncological Applications) in hospital pharmacies and small laboratories.



### ENERGY SAVING

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



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### KEY FEATURES

- Fully PLC controlled isolator system
- Modular configuration concept of the system
- High Efficiency Particulate Air (HEPA H14) filtration
- Unidirectional Air Flow
- Positive/negative pressure gradient achievable
- View/Access panel latches with integrated safety switches
- LED lighting system
- Increased operator safety with better ergonomics
- Compact dimensions allow easy handling through standard doors and elevators in hospitals and pharma companies

### 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 (<0,3 µm), and Scotch Brite external finishing (<0,8 µm)
- Weldings ground, smoothed and polished

### AUTOMATION

- SSIMATIC IPC277E (Nanopanel PC), 7" Touch Panel with TFT colour widescreen display
- PLC Siemens S7-1200
- 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
- Tema Sinergie Data Management System (DataWall) available upon customer request as option

### OPTIONAL INTEGRATED EQUIPMENT

- Integrated VPHP generator (HYPER) and distribution circuit
- VPHP sensor for TLV environment (safety sensor)
- Integrated Non-viable (Particle) monitoring system
- Integrated Automatic Glove Leak Testing System (AGLTS)
- Front Sliding Shield for operator protection, for radiopharmaceutical applications
- Shielded working area for operator protection, for radiopharmaceutical applications
- External Catalytic Unit for H<sub>2</sub>O<sub>2</sub> break down

### 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



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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.