



CC-IS

Cell Culture Isolator System

TEMA SINERGIE
High tech, high care

CC-IS – Cell and Gene Therapy – Regenerative Medicine solutions for tissue-engineered processes. Designed for R&D and cell factories.

Guaranteed asepsis



The CC-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, and exhaust filters
- Single pass 100% extraction airflow
- HYPER, Tema Sinergie's integrated Vapour Phase Hydrogen Peroxide (VPHP) bio-decontamination system.
- Inflatable seals made of FDA-approved White Silicon Bio-Guardian®

Energy Saving



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

Microscope



An integrated microscope for brightfield live cell imaging can be used in routine cell culture processes to monitor cell proliferation, motility and morphology.

Ergonomic design



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

Ease of maintenance



A remote control module made of AISI 316L stainless steel 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 for assistance, updates and maintenance any time, anywhere.

Glove Integrity Testing



The CC-IS can be equipped with an integrated Automatic Glove Leak Testing System (AGLTS 2) 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.

Modular based configuration



The system is based on a versatile modular concept: the base isolator can be easily expanded with additional Process and Transfer chambers. This makes CC-IS perfectly suitable to every requirement and process. A selected group of available options may be added in time.

Automatic leak test



The CC-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).

Data Management



The CC-IS can also be upgraded with an Integrated Supervisory Control And Data Acquisition (SCADA) zenon Software Platform.

+ **Key Features**

Fully PLC controlled isolator system

VPHP resistant anemometer, and relative humidity / temperature (rH%+T) sensor

LED lighting system

Safe change (Bag-In/Bag-Out) filtering units for the process environment

Integrated systems (RTP to transfer solid and liquid products without breaking the aseptic containment

Integrated Flexicon® PD12 Series Peristaltic Pump for flexible and reliable filling processes

Complete Validation package, Installation Qualification/ Operational Qualification (IQ/ OQ) protocol and execution

Cycle Development (CD) protocol and execution upon request

Performance Qualification (PQ) protocol and execution upon request



+ Centrifuge

An integrated centrifuge allows to run the spin cycle on a multitude of cell culture containers and conical tubes for cell passage, and to process a wide range of plates and racks for cell culture analysis.

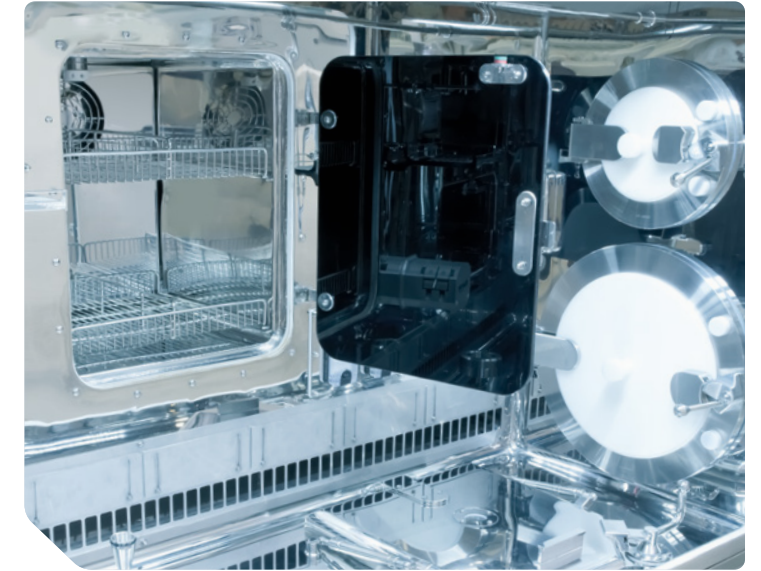
The centrifuge is available with refrigeration capability, and a temperature range of -20° C to +40° C. The centrifuge is integrated into the working place of the Process Chamber.



+ Incubator

An integrated incubator, monitored and controlled through the isolator HMI, guarantees optimal environmental conditions for cell cultures, such as controlled Temperature (T), Humidity (rH%), Carbon Dioxide (CO₂) and Oxygen (O₂).

The incubator is integrated in the back wall of the isolator; an inflatable seal made of FDA-approved White Silicon Bio-Guardian® guarantees the tightness with the Process Chamber.



+ Refrigerator

An integrated refrigerator, monitored and controlled through the isolator HMI, keeps the media and other reagents cool (0 – 20° C).

The refrigerator is integrated in the back wall of the isolator, an inflatable seal made of FDA-approved White Silicon Bio-Guardian® grants the tightness with the Process Chamber.

