



**JCE** BIOTECHNOLOGY

**MANUFACTURER  
OF CUSTOMIZED ISOLATION  
TECHNOLOGY SOLUTIONS**  
SAFETY AND CONTAMINATION CONTROL

# Sterility Test Isolator

*Applications : Industry & Life Sciences*



FC-1-06 Photos are not binding



[www.jcebiotechnology.com](http://www.jcebiotechnology.com)





**MANUFACTURER  
OF CUSTOMIZED ISOLATION  
TECHNOLOGY SOLUTIONS**  
SAFETY AND CONTAMINATION CONTROL

**Innovation**

**Sterility Test Isolator**

Whatever your challenge, JCE Biotechnology can provide you with a tailor-made answer through the design of a customized turnkey solution.

**Safety**

**JCE Biotechnology's technical solution includes:**

- The study, design, tailor-made manufacture and commissioning of the isolator and its accessories;
- The air handling and H<sub>2</sub>O<sub>2</sub> (hydrogen peroxide) decontamination system of the isolator;
- The instrumentation required for the installation to work as it should;
- Systems qualification (design, installation, operational validation and performance);
- User training at the end of qualification.

**Ergonomics**

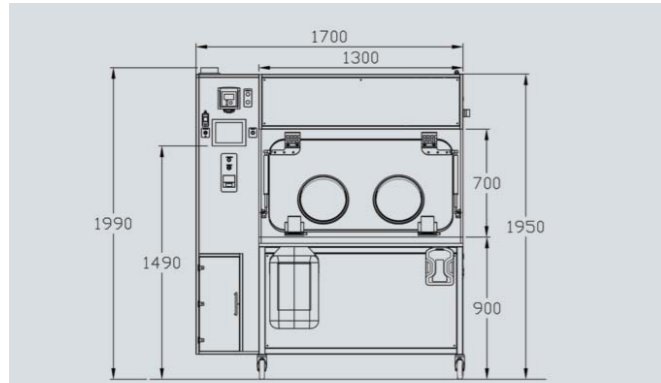
**Flexibility**



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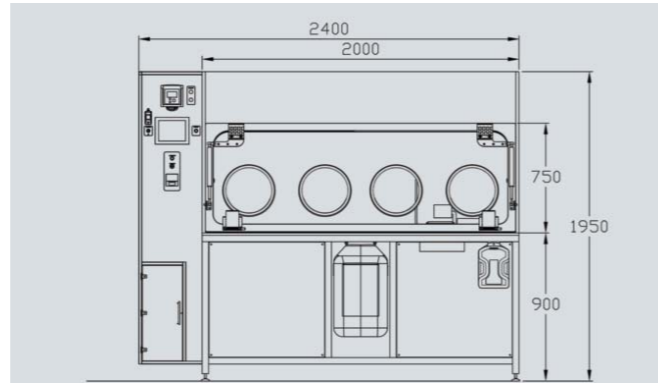
# The JCE Biotechnology concept

Using two basic configurations, JCE Biotechnology offers a wide range of custom-developed isolators and accessories to fit your specific requirements.



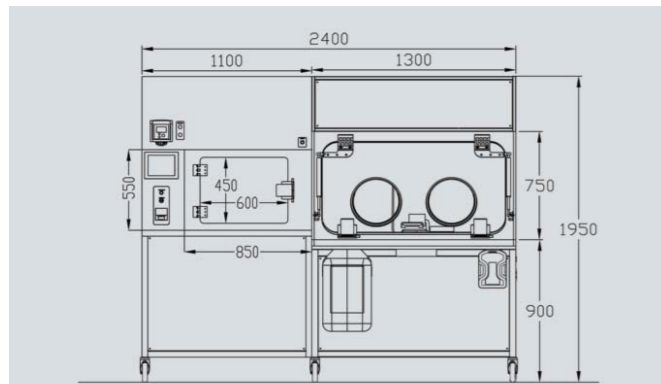
**ITS2G Configuration**

- Introduction via hatch
- 1 two-glove test isolator
- 1 integrated H<sub>2</sub>O<sub>2</sub> bio-decontamination system
- 1 MWS150A® system for the disposal of solid waste
- 1 MWS50A® system for the disposal of liquid waste
- Turbulent or Laminar Unidirectional air flow handling system
- Monitoring, control and supervision accessories.



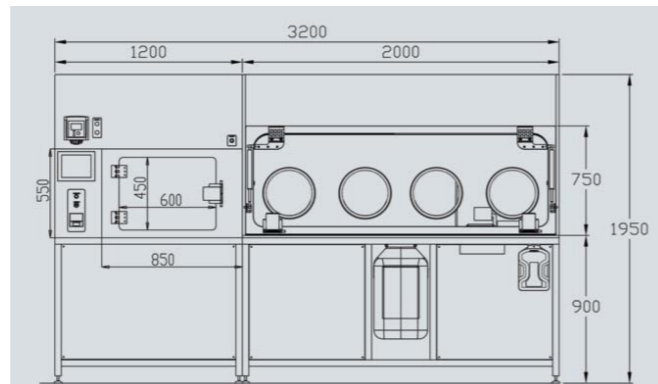
**ITS4G Configuration**

- Introduction via hatch
- 1 four-glove test isolator (possibility 3 gloves on demand)
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**ITS2GS Configuration**

- 1 introduction airlock
- 1 two-glove test isolator
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**Optional accessories:** Millipore Steritest or other models - Microbial air sampler  
Particle counter - Glove/Sleeve tester - Product outlet via tubing - Catalytic H<sub>2</sub>O<sub>2</sub> system.

**Please ask us about other custom-made characteristics and dimensions**

# Applications in a safe environment

The quality of JCE Biotechnology solutions guarantees the prevention of any risk of contamination during manipulation, sterility testing and transfer.

## Operation

- Introduction of pharmaceutical batches, canisters, vials, ampoules, gels and test accessories
- 35% H<sub>2</sub>O<sub>2</sub> bio-decontamination cycle with a 6 Log reduction of Geobacillus stearothermophilus spores (ATCC 7953 or ATCC 12980) lasting 15' to 60' depending on configuration and airlock load
- Aeration phase down to 1 ppm of H<sub>2</sub>O<sub>2</sub> residual rate monitored
- Tests performed via integrated Millipore Symbio pump
- Disposal of solid and liquid waste via MWS outlet system
- Batch exit (depending on configuration) via the hatch, tubing or introduction airlock.

## Main features

- Isolator and airlock made of 316L stainless steel 3 mm thick Ra <0.5 μ
- Smooth, cleaned and passivated welds electropolished finish
- 20 mm rounded corners
- 304L electropolished finish stainless steel safety guards
- 304L stainless steel G220 brushed finish base on self-braking castors or adjustable legs
- Dimensions: as per defined model (see technical drawing dimensions on page 2)
- Work surface height: 900 mm
- Centrifugal fan up and downstream
- Class A Turbulent or Laminar unidirectional airflow operating at 0.45m/s +/- 20%
- Average airflow extraction of 100 to 400 m<sup>3</sup>/h depending on configuration
- Air change rate > 50 Volume/h depending on configuration
- Operation: Positive or Negative pressure set with configurable setpoints at +/- 50 Pa
- HEPA H14 filtration up and downstream of the isolator
- Particulate classification: Iso 4.8 as per ISO14644-1
- Motorised valves on ventilation system
- Isolator in leak rate class 2 as per ISO 10 648-2
- Leak rate: 0.5% vol/h at 150 Pa
- Sound level < 65 db as per NF EN 12649
- Safety glass viewing window on hatch with inflatable silicone seal
- Internal and external transfer doors interlocked with inflatable silicone seal
- 2 or 4 PE/PVC sleeves for manipulation
- 5/10 neoprene gloves on front
- Glove ring: 300 mm in diameter.



## Integrated accessories and tailor-made solutions

Whatever your requirements, JCE Biotechnology designs your tailor-made solution thanks to its full range of accessories, fitting in with any type of installation. You can remain focused on your job.

Discover the JCE Biotechnology range of accessories

### 1 / Transfer airlock and Hatch



#### Principle

Pharmaceutical products and batches are introduced via a transfer airlock or via a hatch with interlocked doors and inflatable seals to ensure perfect leak-tightness.

The transfer airlock or the hatch mounted on gas pistons and inflatable seal guaranteeing perfect leak-tightness, can also be used to evacuate tested batches.

#### Configuration

Materials, dimensions and design of the custom-made airlock as per the use required, including racks, sliding trays, trolleys, etc.



### 2 / H<sub>2</sub>O<sub>2</sub> Generator



#### Principle

Sterilization or bio-decontamination is a validated process used to make the environment of an isolator or any other closed system free from viable micro-organisms by using an anti-microbial gas.

#### Operation

The product used is hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>) at a concentration of 35%. Sterilization or bio-decontamination is certified conform after a 6 Log destruction of Geobacillus Stearothermophilus biological indicators ATCC 7953 / ATCC 12980. The sterilization cycle takes place in 3 phases: phase 1 conditioning with relative humidity control, phase 2 vaporization and phase 3 aeration.

### 3 / Secure Transfer System



#### Containers

- IHW standards (Infectious Healthcare Waste) NFX30 511, UN3291, UN3249
- Gamma sterilised at 25 kGy.

#### Solid waste

Positioned on the work surface, this RTP security version door system (MWS150A®) will be used to dispose of waste without loss of containment, while ensuring protection of personnel and the containment area.

#### This device can include:

- Flexible PVC containers holding 50 or 100 litres
- Rigid PE containers holding 50 litres.



#### Liquid waste

Positioned on the work surface, this RTP security version door system (MWS50A®) will be used to dispose of waste without loss of containment, while ensuring protection of personnel and the containment area.

#### This device can include:

- A rigid PE container holding 5 litres.

## 4 / Isolator Monitoring



### Principle

- Isolator control and monitoring via IHM SIEMENS
- H<sub>2</sub>O<sub>2</sub> generator control and monitoring
- Reference documents: Gamp5, 21 CFR Part 11, GMP, current European Pharmacopoeia.

### Leak test

- Built-in, automatic leak test
- Test by pressure drop
- Class 2 as per ISO 10648-2.

### Operation

- 230V 50 Hz power supply
- Protection with 20A and 300mA differential circuit breaker
- 3G2.5 isolator cable
- 4G2.5 shielded cable for external extractor
- External evacuation Ø 200 mm PVC leakproof pipe
- RJ45 for remote maintenance
- 6 bar pressure plant compressed air (customer supply).



## 5 / Accessories



### Sleeve support

Stainless steel rod support system to keep the sleeve and glove suspended without outside contact during bio-decontamination phases.



### Shelves

- 316L stainless steel trays
- Dimensions and quantities as per URS.



### H<sub>2</sub>O<sub>2</sub> Sensor

External H<sub>2</sub>O<sub>2</sub> low concentration sensor.

- Polytron 7000
- Measures 0.10 ppm
- Output 4.20 mA.



### Utilities connector board

- Placed on the rear of the isolator
- Cable, clamp and electricity plug port
- Quantity and model as per URS.

## 6 / Additional accessories



### Millipore Steritest

Designed for testing in an isolator.

- Integrated to customer order or directly by JCE Biotechnology.



### Particle counter

Measures particle concentration in production phase.

Make and model of device as per URS.

Permanent integration possible.

- 0.5 and 5µ count in real time
- Flow: 1 CFM
- Analog output or RS232.



### Product outlet via tubing

Placed on the side of the isolator, the tubing system provides the means to safely evacuate and package the products manufactured and controlled.

- Secure door MWS 150 AT®
- Packaged in PVC sheath, 5 metres long
- Gamma sterilized at 25 kGy
- Impulse welder
- 400 mm-long double weld
- Magnetic locking.



### Microbial air sampler

Monitors microbiological contamination in production phase.

Make and model of device as per URS.

Permanent integration possible.

- 90 to 100 mm Petri dish
- Digital output.



### Glove/Sleeve tester

Automatic glove and sleeve tester.

- Integrated compressor
- Test by pressure drop
- Maximum pressure use 1000 Pa.



### Catalytic system

H<sub>2</sub>O<sub>2</sub> Catalyser (transformation into residue-free water and oxygen)

- Can be released into the room
- No external connection required
- Release < 1 ppm controlled by low concentration sensor
- Integrated extraction fan.

## Qualification / Validation Services

Design

Testing, qualification and validation of physical and bacteriological processes, isolators, clean rooms and clean areas.  
JCE Biotechnology provides proof by demonstrating.

Installation

**Discover all of JCE Biotechnology's services**

### Qualification

Operation designed to show that the equipment works correctly and actually delivers the expected results. The validation concept is sometimes expanded to include qualification activities.

### Validation

Provides evidence, in compliance with GMP, that the implementation or use of processes, procedures, materials, raw materials, packaging articles or products, activities or systems actually makes it possible to achieve the expected results.



### Systems Qualification Design Qualification

To check that the installations and equipment to be put in place on the basis of the design plans have been correctly designed according to the reference, technical and standards criteria. This also involves defining specifications for the equipment in line with environmental requirements.

### Installation Qualification (IQ)

To provide documented proof that the equipment complies with the specifications and to check the presence of related documentation.

### Operational Qualification (OQ)

To provide documented evidence that the system operates according to the functional analysis and to the supplier's recommendations.

### Performance Qualification (PQ)

To check the performance of the installation within its range of use according to the required operating method.

## Technical support and maintenance

After-sales



Reactivity and quality of service.  
JCE Biotechnology is there to support you and to guarantee the uninterrupted running of your equipment, by optimising its availability and operability, while keeping within your budget constraints.

**Discover all of JCE Biotechnology's services**



### Technical Support Hotline

**Telephone: +33 (0) 470 595 149**  
**Fax: +33 (0) 470 595 141**  
**e-mail: sav@jcebiotechnology.com**



We will analyse your requests so as to provide you with an appropriate solution without delay.  
When an on-site call-out is necessary, a JCE Biotechnology technician will be sent to you as quickly as possible depending on time constraints and location.  
This system allows us to remain proactive and to satisfy our customers.

### Service contracts

In addition to the warranty conditions in place following the installation of new equipment, JCE Biotechnology offers a range of preventive and corrective maintenance solutions tailored to your needs, to ensure your equipment operates at full capacity and your costs are kept under control.

### Remote maintenance

When putting new equipment into service and depending on the configuration, we will install a device to enable remote-maintenance service of your equipment. For further information on installation and operating conditions please contact us.





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