

NEW MSTI

MODULAR STERILITY TESTING ISOLATOR



YOUR BATCH RELEASE INSURANCE



PHARMA



COMECER

an  company

NEW MSTI

MODULAR STERILITY TESTING ISOLATOR

The Modular Sterility Testing Isolator has been conceived for lab professionals who require aseptic conditions for sterility testing of pharmaceutical products.

- Fully closed environment in Grade A that can be installed in Grade D areas



- Full Laminar Air Flow



- VPHP decontamination system



- Dedicated loading racks/basket for material loading



- Suitable for testing of vials, ampoules, syringe, cartridge and others



- Panel PC HMI Control System fully compliance for CFR21 Part11 and Data Integrity requirements



A real modular approach

Several modules are available. Desired configuration based on the specific customer need is reached combining the different modules.



Customized internal solutions

The MSTI can be equipped with customized racks, accessories and tools in order to answer any specific requirement.

A dedicated load study is carried out to correctly host and position all the samples, such as vials, ampoules, bags, syringes as well as consumables like saline solution, culturing media, petri dishes.

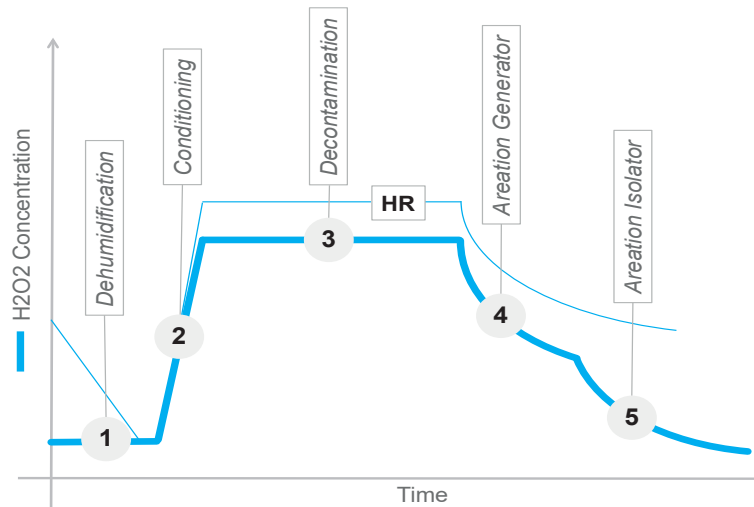
NO MATERIAL LOADING LIMITATION !



The heart of MSTI: integrated VPHP decontamination system

An integrated VPHP generator assures the 6-log decontamination of all the internal volumes in the shortest time. Full cycle reporting is provided through the main isolator HMI.

FAST DECONTAMINATION CYCLE



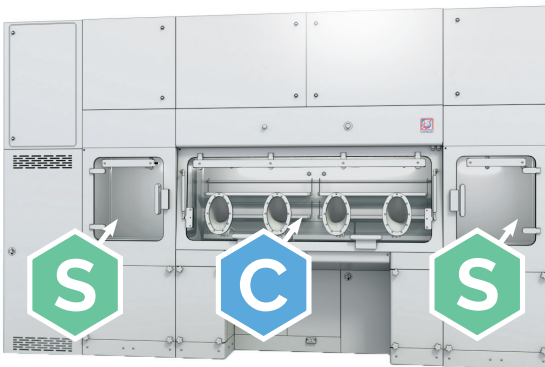
General process cycle

Each phase of sterility testing, either following Direct Inoculation method or Membrane Filtration method, has its own need.

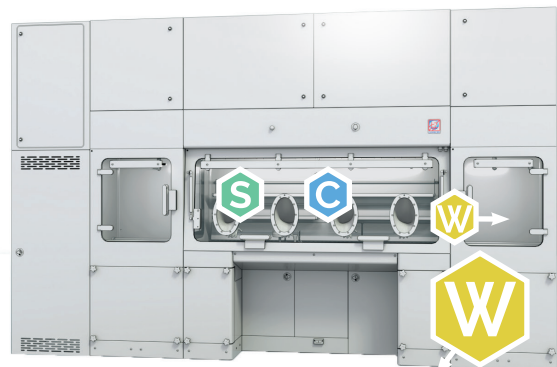
MSTI is configured in order to assist the operator step by step, always ensuring the best performances and maximum comfort.

 ST Consumables  Sample  Waste

1. Material loading



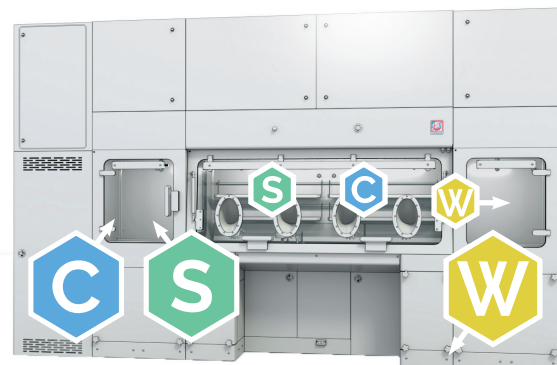
3. Sterility testing



2. Decontamination cycle



4. Materials loading during sterility testing



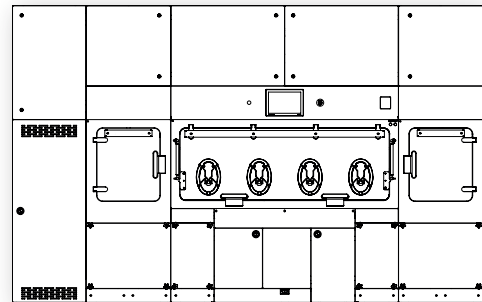
Further available options

- Glove Tester **SPEEDY GLOVE**
- RTP Rapid Transfer Port
- Integrated Peristaltic Pump for Sterility Testing
- Viable and Non Viable Monitoring System Integrated
- HEPA H14 1st stage exhaust filtration
- HEPA H14 2nd stage exhaust filtration BIBO Safe Change
- Catalyzer for Stand Alone installation
- Scada interface Predisposition

Technical data

Material	
Shell structure	AISI 316 L
Stainless steel finish	external: Scotch-Brite internal: Mirror-Brite
Air classification	
Main chamber	class A (after decontamination)
Pre-chamber	class A (after decontamination)
Working internal pressure	
Main chamber	50-100 Pa
Pre-chamber	25-50 Pa
Filters	
Main chamber	H14 inlet (outlet filters upon request)
Pre-chamber	H14 inlet (outlet filters upon request)
Make up air flow rate	1050 m ³ /h
Overall dimensions (w x d x h)	4650 x 1500 x 2550 mm
Internal dimensions (w x d x h)	
Main chamber	1900 x 750 x 700 mm
Pre-chamber	700 x 600 x 700 mm
Net weight	2900 kg
Utilities requirements	
Compressed air	6 bar, 25 nL/min
Power supply	
Isolator	230V (1Ph+N+PE) 50/60Hz 32A TN-S
VPHP generator	230V (1Ph+N+PE) 50/60Hz 25A TN-S
Installed power	8900 W

NEW MSTI



ALL DATA REFER
TO THE CONFIGURATION:
VPHP
PRE-CHAMBER L
CHAMBER
PRE-CHAMBER-R



COMECER S.p.A. - Via Maestri del Lavoro, 90
48014 - Castel Bolognese (RA) - Italy
t: +39 0546 656375 - f: +39 0546 656353
comecer@comecer.com - www.comecer.com



www.comecer.com/MSTI