# IsoFACT Sterility Isolator System

## Designed for GMP-Compliant Sterility Testing & Aseptic Processing


The BIOMATRIX IsoFACT Sterility Isolator System provides a fully enclosed aseptic environment for pharmaceutical and biotechnology applications. Integrating advanced VHP bio-decontamination, Grade A unidirectional airflow, intelligent pressure control, and real-time monitoring, IsoFACT reduces contamination risks while ensuring reliable sterility assurance and GMP-compliant operation.

The system supports automated sterilization, leak testing, electronic records, audit trails, and process traceability compliant with GMP and FDA 21 CFR Part 11 requirements. IsoFACT is widely used for sterility testing, aseptic processing, pharmaceutical QC laboratories, and other contamination-sensitive applications.

## KEY FEATURES

- **Integrated VHP Bio-Decontamination**
  Advanced aVHP technology delivers rapid and effective bio-decontamination with validated >6-log microbial reduction.
- **Grade A Unidirectional Airflow**
  H14 HEPA filtration delivers stable Grade A airflow conditions for reliable aseptic protection.
- **Fast Decontamination Cycle**
  Optimized sterilization and aeration processes enable fast turnaround within 2.5 hours.
- **Low-Temperature Sterilization**
  Minimal chamber temperature rise during VHP cycles protects temperature-sensitive biological products and sterile materials.
- **Fully Sealed Hard-Wall Chamber**
  Robust hard-wall structure with inflatable sealing technology ensures excellent containment and low leakage performance.
- **Data Integrity Compliance**
  Supports electronic records, audit trails, batch management, and FDA 21 CFR Part 11 compliance.
- **Intelligent PLC Control System**
  Touchscreen HMI with automatic/manual operation, parameter management, and multi-level user access control.

## APPLICATIONS

- Sterility Testing: Designed for pharmaceutical sterility testing under fully aseptic conditions.
- Aseptic Processing: Suitable for aseptic transfer, filling, and contamination-sensitive operations.
- Biotechnology: Widely used in biological products, cell therapy, and gene therapy applications.
- Pharmaceutical QC Laboratories: Provides reliable contamination control for microbiological quality control environments.
- Research & Development: Ideal for laboratories requiring validated aseptic containment systems.

## OPTIONAL CONFIGURATIONS

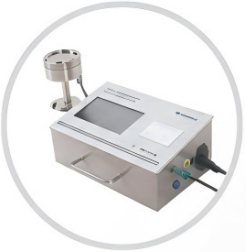
Video Monitor


Infrared Barcode Scanner


Waste Discharge System


Particle Counter


Barcode Printer


Air Sampler


Ampoule Opener

$H_2O_2$ Concentration Sensor


Fully Automatic Ampoule Opener


Built-in Sterility Test Pump

## COMPLIANCE & VALIDATION

### Compliance Standards
- GMP
- FDA Guidelines
- EU GMP Annex 1
- FDA 21 CFR Part 11
- USP
- EP

### Validation Support
- DQ
- FAT
- SAT
- IQ
- OQ
- PQ

### Documentation Support
- Calibration records
- Validation documents
- Electrical drawings
- Operating manuals
- Maintenance manuals
- Test reports

## TECHNICAL SPECIFICATIONS

| Model | IsoFACT 2T | IsoFACT 3T | IsoFACT 4T |
|---|---|---|---|
| Number of Gloves in Main Chamber | 2 | 2 | 4 |
| Number of Operators | 1 | 1 | 2 |
| Overall Dimensions W x H x D | 2270*850*2430 | 2217*1160*2170 | 2417*1160*2170 |
| Main Chamber Internal Dimensions, W x H x D, in mm | 1200*630*700 | 1595*650*700 | 1795*650*700 |
| Transfer Chamber Internal Dimensions, W x H x D, in mm | 595*515*700 | 595*515*700 | 595*515*700 |
| Chamber Type | Rigid Wall Isolator | | |
| Material of Construction | SUS304、SUS316L | | |
| Chamber Cleanliness Classification | Dynamic Grade A (As Required) | | |
| Power Supply | AC220V±22V | | |
| Frequency | 50Hz±1Hz | | |
| Power Consumption | 3500W | | |
| Control System | Siemens PLC | | |
| Hydrogen Peroxide Concentration During Decontamination | 400-500PPM | | |
| Chamber Pressure Control Range | -80-80Pa | | |
| Leakage Rate | ≤0.5%vol/h | | |
| Noise Level | ≤75dB（A） | | |
| Main Chamber Supply Air Filter | HEPA, H14 | | |
| Transfer Chamber Supply Air Filter | HEPA, H14 | | |
| Main Chamber Return Air Filter | HEPA, H14 | | |
| Transfer Chamber Return Air Filter | HEPA, H14 | | |
| Illumination | ＞300LX | | |
| Isolator Airflow Pattern | Laminar Flow | | |
| VHP Decontamination Cycle Time | Transfer Chamber: ≤35 min, Main Chamber: ≤70 min | | |
| Chamber Temperature Rise | 1℃-3℃ | | |
| Sterilant Solution | 30% Hydrogen Peroxide Solution | | |
| Decontamination Efficiency | SLR＞6 | | |
| Standard Features | 21 CFR Part 11 Audit Trail | | |
| | SCADA Software Architecture | | |
| | Automatic Leak Testing | | |
| | Positive Pressure | | |
| | PAO/DOP Test Port | | |
| | Compressed Air Dehumidification | | |
| | Desiccant Dehumidification | | |
| | Differential Pressure Gauge | | |
| | Temperature & Humidity Sensor | | |