ISOFLEX

Multi-purpose and tailored to your process

GETINGE

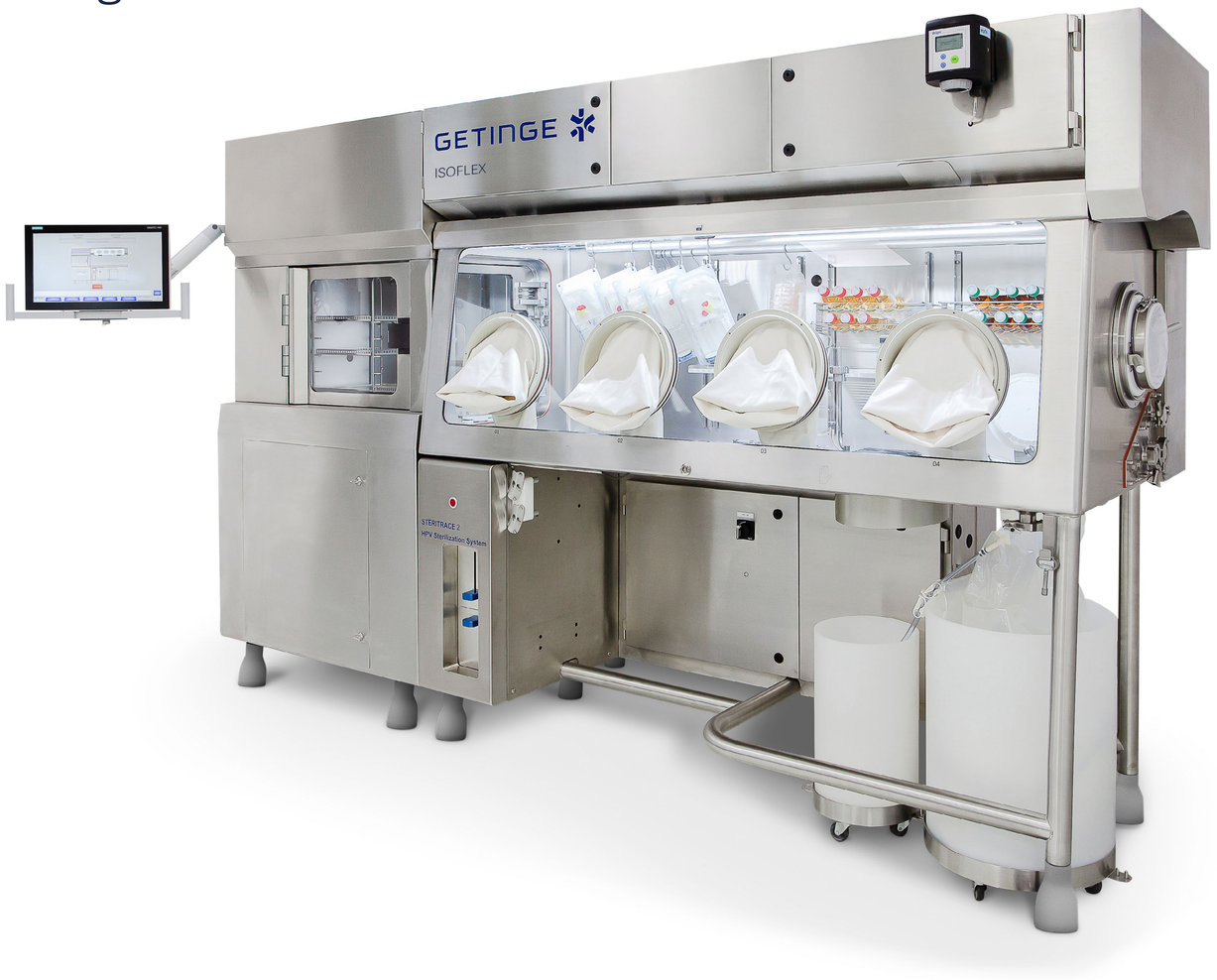
A modular, rigid-wall isolator

The answer to your daily needs for aseptic processing

Protect against contamination during sterile applications. ISOFLEX Isolators maintain an enclosed and sterile environment for aseptic operations.

In biopharmaceutical production, healthcare and many other markets, it's critical to create and maintain aseptic conditions throughout transfer, manipulation, and bio-decontamination. The modular, rigid-wall ISOFLEX Isolator offers the flexibility you want, with the process controls that you require.

A large front glass window can be easily opened for fast and ergonomic loading. ISOFLEX is compatible with our full range of DPTE® Transfer Solutions to ensure safe and efficient transfer without breaking containment.



Two types of ventilation to maintain aseptic conditions

With the ISOFLEX, choose from unidirectional or turbulent airflow to meet various process requirements. In this sealed, operator-free environment with control over sources for contamination entry (HEPA filters, transfer ports), engineered turbulent flow (ETF) is sufficient to maintain sterile conditions. However, for aseptic applications where it is important to ensure that non-viable particles are rapidly swept away from critical areas, unidirectional airflow (also known as UDAF, LAF, laminar flow) is appropriate to meet Grade A/ISO 4.8. When handling sterile APIs, a HEPA filter with safe changeover is available as an option.

Validated process control and traceability

ISOFLEX offers either a Siemens or Rockwell Allen Bradley PLC for process control and monitoring. Both control systems are equipped with a 19" color touch panel PC with an intuitive user interface for easy navigation, operation, and parameter monitoring. User access is easily managed and adapted to your needs using a non-pyramidal structure.

ISOFLEX provides standard, Windows 10 based, built-in SCADA for central supervision of process performance. Authorized users can adjust process parameters according to the unique requirements of a specific process. Batch reports can be digitally stored locally or in the user's network. The system allows you to choose up to two signatories. ISOFLEX is fully FDA 21 CFR Part 11 and GMP Annex 11 capable and compliant.

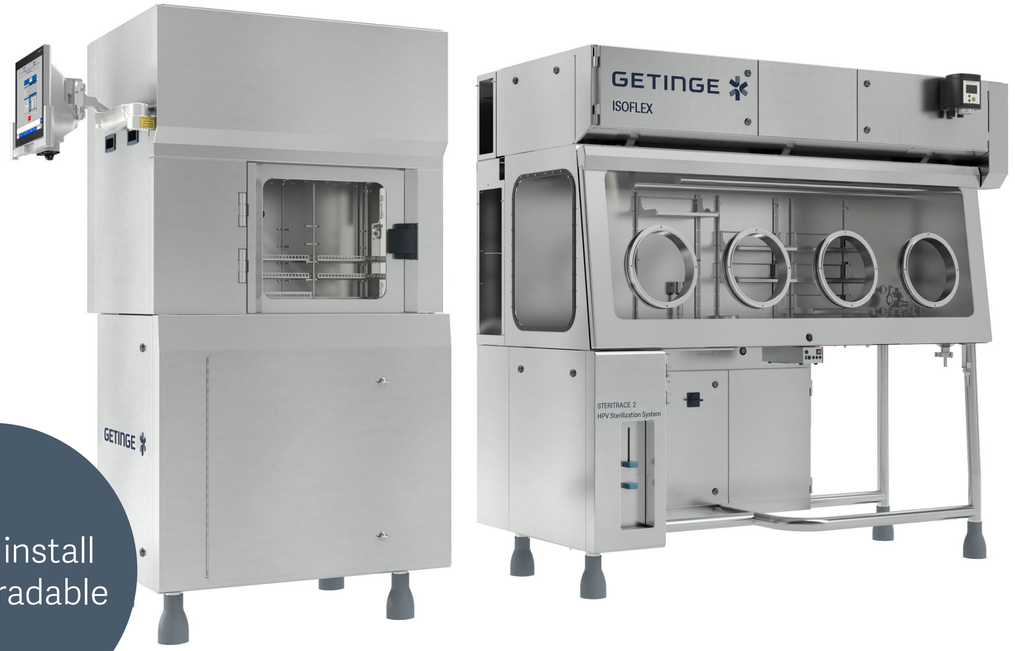
A modular design maximizes flexibility needs, today and tomorrow

Configured to your specific needs, today and tomorrow

Modular design for flexible use

The modular design of the ISOFLEX allows the isolator to be configured and to evolve according to your specific needs. Three-glove versions are available for a single operator, while four-glove versions allow two operators to work simultaneously.

Bio-decontamination hatches can be added at one or both ends of the isolator. HMI can be positioned on the left or right side depending on your need or site constraints.



Easy to install and upgradable

3-glove UDAF ISOFLEX

3-glove ETF ISOFLEX

3-glove ETF ISOFLEX
with hatch and (H_2O_2) catalytic converter

4-glove ETF ISOFLEX
with hatch and (H_2O_2) catalytic converter

4-glove ETF ISOFLEX
with hatch

4-glove ETF ISOFLEX
with integrated glove leak tester (GLT)

Accessoires and options

Bio-decontamination alternatives

When it comes to bio-decontamination, the ISOFLEX provides the means to bio-decontaminate the isolator working chamber, the hatch, or both chamber and hatch simultaneously. The integrated H_2O_2 generator ensures safe operations and reliable processes. The unit is controlled by the same interface as the isolator and provides full traceability of H_2O_2 bottles.

Standalone wireless glove leak tester (GLT)

Integrated monitoring devices

- H_2O_2 sensors for operator safety
- Active air sampler
- Non viable particle
- Wireless glove leak tester (GLT)

Shelving solutions

- Basic shelves
- Modular shelves
- Hatch shelves and baskets: space saving and no risk of surface contamination transfer

Connectivity and reporting

- Isolator connected to customer network
- User management with connection to active directory
- Periodical back-up of SQL data base
- Data integrity
- Use of network printer
- Traceability with archived batch reports on network

Other typical accessories

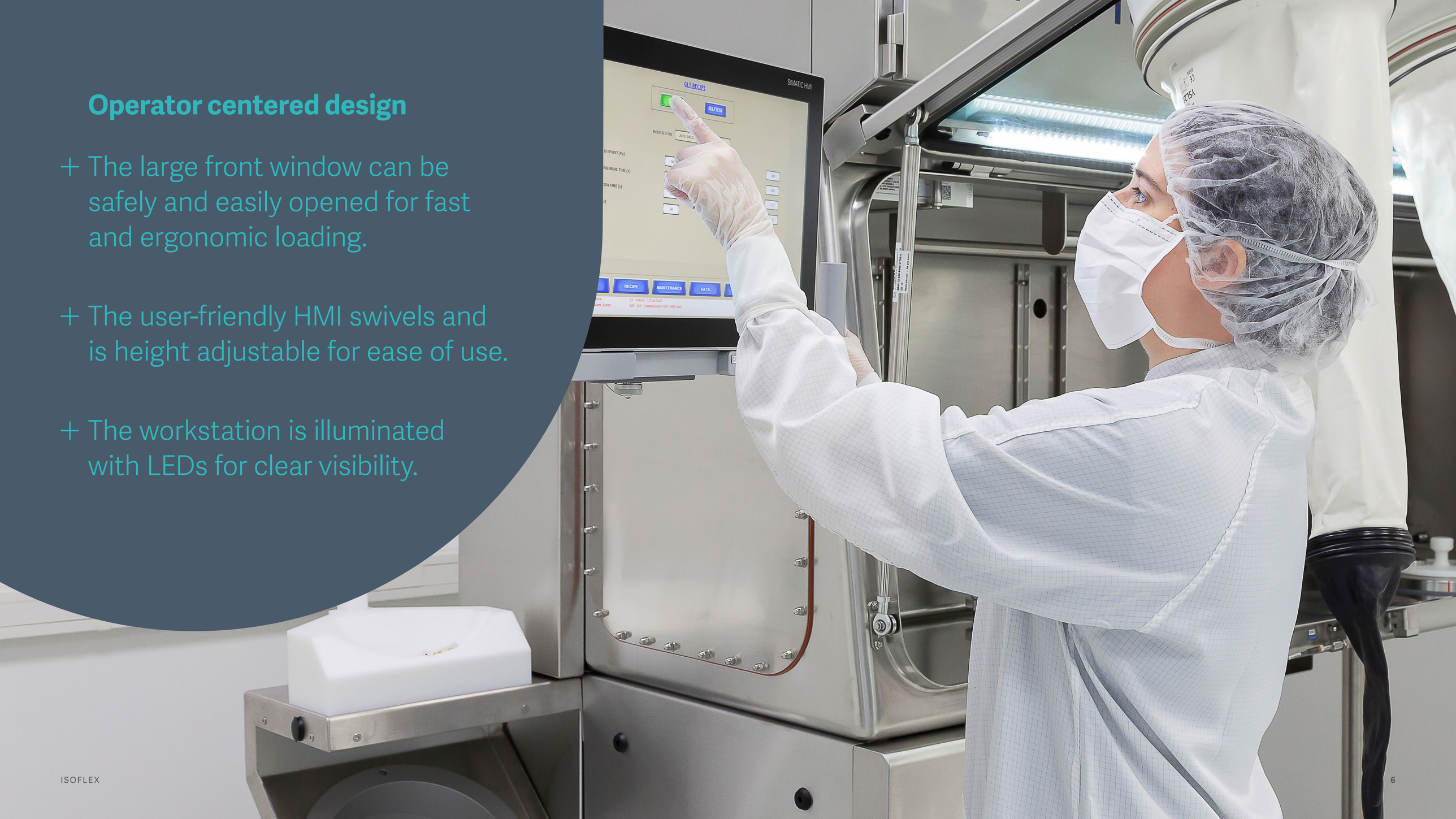
- Dismountable hanging bars with hooks
- Service plate with tri-clamp passthroughs and cable glands
- H_2O_2 catalytic converters
- Integration of peristaltic pump for membrane filtration
- Sleeve extenders with finger separators
- and many more accessories …

Operator centered design

+ The large front window can be safely and easily opened for fast and ergonomic loading.

+ The user-friendly HMI swivels and is height adjustable for ease of use.

+ The workstation is illuminated with LEDs for clear visibility.



Sterile applications

Multipurpose and tailored solutions

DPTE® transfer systems

Application-specific options for comfort and safety

DPTE® Alpha

The core of the DPTE® transfer system is the Alpha port: a secure interlock enables totally safe connections and disconnections. The DPTE® system allows material to be moved from one sterilezone to another through a non-sterile zone, with leak-tight, risk-free reconnection.

DPTE® Beta Containers

Stainless steel or plastic DPTE® Beta Containers allow for safe transfer into and out of a barrier system. Autoclavable, stainless steel and plastic inserts enable you to sterilize and transfer tools etc.

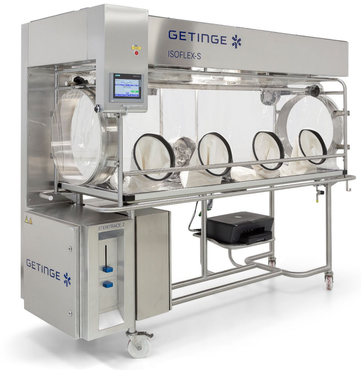
DPTE-BetaBag®

The DPTE-BetaBag® is a combination of a DPTE® Beta part and a bag for the safe transfer of sterile products or waste material. The DPTE-BetaBag® single-use range is designed for fast contamination-free transfer to maintain high-speed production, increase flexibility and minimize validation costs.

Safe and efficient waste handling

A dual-waste DPTE-BetaBag® allows for safe removal of liquid and solid waste from the isolator. The DPTE® system provides egress from inside the isolator chamber while maintaining isolator integrity; there is no risk of sample or environmental contamination. It’s a useful solution for handling cytotoxic waste.

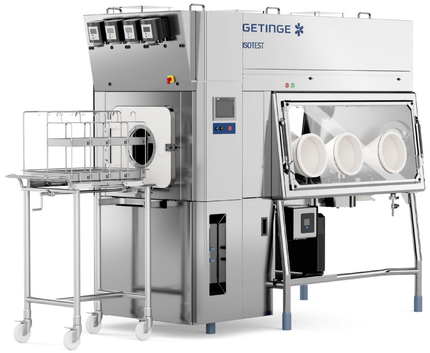
Other standard isolator solutions from Getinge



ISOFLEX-S Isolator
A transparent, flexible-wall isolator

The ISOFLEX-S Isolator has transparent semi-rigid plastic walls that provide a panoramic view of the working area. ISOFLEX-S Isolators combine the robustness of a 316L stainless steel working base with the comfort of working with glove sleeves on a flexible wall.

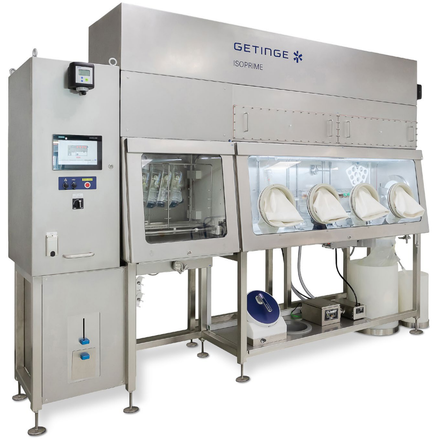
- Flexible and mobile
- User-friendly operations
- Modular design
- Validated process control and traceability
- Cost effective solution



ISOTEST Isolator
Efficient and reliable sterility testing processes

ISOTEST is an isolator designed for sterile applications, including sterility testing of sterile drugs, components, and devices. Continuous workflow, easy access, and fast bio-decontamination help to increase productivity.

- Dual workstation with capacity to combine two test methods
- Optimized workflow
- Minimize downtime for improved throughput
- Effective bio-decontamination
- Validated process control and traceability



ISOPRIME Isolator
Optimized for common aseptic applications

The ISOPRIME is the ideal solution for customers with modular rigid-wall isolator requirements that combine high-quality, versatility and continuous operations at a competitive price point.

- Operator-friendly access
- Direct access for maintenance
- Cost effective solution
- Two types of ventilation to maintain aseptic conditions:
  - Engineered Turbulent Flow (ETF)
  - Unidirectional AirFlow (UDAF)

GETINGE

With a firm belief that every person and community should have access to the best possible care, Getinge provides hospitals and life science institutions with products and solutions aiming to improve clinical results and optimize workflows. The offering includes products and solutions for intensive care, cardiovascular procedures, operating rooms, sterile reprocessing and life science. Getinge employs over 10,000 people worldwide and the products are sold in more than 135 countries.

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