

ISOFLEX-S

Work in comfort with clear visibility



A transparent softwall isolator

Your panoramic view of the working area

Regulatory agencies require sterility testing of pharmaceutical products to ensure sterile batch. ISOFLEX-S Isolators provide a safe controlled environment that is cost effective for reliable testing procedures.

When sterility testing pharmaceutical products, there is no room for error. Modular ISOFLEX-S Isolators are designed for flexible, user-friendly operation that delivers accurate, reproducible results.

The ISOFLEX-S Isolator has transparent semi-rigid plastic walls for comfortable work with clear visibility.



Flexible and mobile

Castors allow the ISOFLEX-S Isolator to easily move and connect to other isolators or filling lines using Getinge's patented DPTE® system. With its integrated Hydrogen Peroxide (H_2O_2) generator, it can also be used as a mobile bio-decontamination unit.

User-friendly operations

The flexible wall allows operators to push and pull the soft canopy for comfort and accessibility. Transparent PVC provides a panoramic view and 360° visibility of the working area, tools and components. The base is constructed from robust, polished 316L stainless steel for easy and efficient cleaning and solidity.

Modular design

ISOFLEX-S is available in three- or four-glove configurations. The three-glove isolator (1.5 m long) is designed for one operator and offers a large storage capacity. The four-glove configuration (2 m long) provides working capabilities for two operators simultaneously. The DPTE® transfer system can be installed in the base of the isolator and at both ends, instead of the standard lateral doors hence increasing contamination control.

Validated process control and traceability

Both the isolator and integral bio-decontamination unit are controlled by a single Siemens PLC control system. Reports are sent to an integrated printer or remote PC (option). Data and reports can be stored in the built-in FDA 21 CFR part 11 compliant SCADA and in the customer network (option).

The color touchscreen control panel provides intuitive and easy operation. Through the HMI, authorized users can set process parameters that operators can easily monitor during the process.

Manipulation devices

Application-specific options for comfort and safety

Getinge isolators can be provided with different application-specific manipulation systems that match the process inside the isolator to the operator's hand.

The glove sleeve offers protection and easy maintenance. An O-ring system allows the glove to be replaced without breaking sterility. The system is designed for use with the paperless glove leak tester (GLT) for seamless in-situ glove testing. This provides a complete package that is safe, comfortable, practical, and able to be validated for regulatory compliance.



Integrated bio-decontamination: Steritrace

The built-in bio-decontamination unit uses Hydrogen Peroxide Vapor (HPV), a proven sterilant commonly used in the pharmaceutical industry. It is generated from liquid Hydrogen Peroxide (H_2O_2) from a bottle fitted with an RFID (Radio Frequency Identification) device, that is placed in a receptacle on the isolator.

The generator checks the validity of the HPV bottle and the batch number is recorded in the process report. Steritrace is controlled by the same PLC as the isolator unit, thus minimizing components and enabling validation and maintenance of a single piece of equipment.





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 Isolator A modular, rigid-wall isolator

The ISOFLEX Isolator protects the product against contamination during aseptic operations such as sterility testing. The rigid-wall isolator maintains an enclosed and sterile environment throughout transfer, manipulation, and bio-decontamination.

- Modular design for flexible use
- Validated process control and traceability
- Two types of ventilation to maintain aseptic conditions:
- Engineered Turbulent Flow (ETF)
- Unidirectional Air Flow (UDAF)



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)

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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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