



ISO FLEX-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. Getinge 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 Getinge ISOFLEX-S isolator has transparent semi-rigid plastic walls for comfortable work with clear visibility.



Flexible and mobile

Castors allow the Getinge 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 (H₂O₂) 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

Getinge ISOFLEX-S is available in three- or four-glove configurations. The three-glove isolator (1.5m long) is designed for one operator and offers a large storage capacity. The four-glove configuration (2m 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.



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 (H₂O₂) 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.

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.



A robust 316L stainless steel working base combined with the comfort of glove sleeves and a flexible, fully transparent wall.

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 sterile zone to another through a non-sterile zone, with leak-tight, risk-free reconnection.



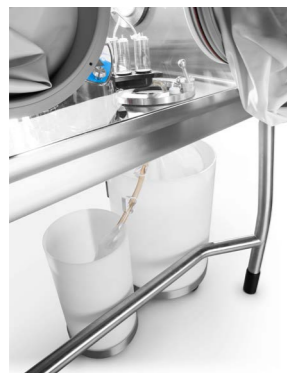
DPTE-BetaBag®

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.



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.



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

Getinge ISOFLEX-R Isolators



A modular, rigid-wall isolator

The Getinge ISOFLEX-R 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) and Unidirectional AirFlow (UDAF)

Getinge ISOTEST Isolators

Efficient and reliable sterility testing processes

Getinge 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





Getinge is a global provider of innovative solutions for operating rooms, intensive care units, sterilization departments and for life science companies and institutions. Based on our firsthand experience and close partnerships with clinical experts, healthcare professionals and medtech specialists, we are improving the everyday life for people - today and tomorrow.

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