



## ISO-FLEX-R

Multi-purpose and tailored  
to your process

# A modular, rigid-wall isolator

## The answer to your daily needs for aseptic processing

Protect against contamination during sterile applications. Getinge ISOFLEX-R 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 Getinge ISOFLEX-R 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. Getinge ISOFLEX-R 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 Getinge ISOFLEX-R, 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.

### Validated process control & traceability

Getinge ISOFLEX-R 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.

Getinge ISOFLEX-R 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. Getinge ISOFLEX-R is fully FDA 21 CFR Part 11 and GMP Annex 11 capable and compliant.

# A modular design maximizes flexibility

Configured to your specific needs, today and tomorrow

## Modular design for flexible use

The modular design of the Getinge ISOFLEX-R 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, or between two isolators.



3-glove UDAF ISOFLEX-R



4-glove ETF ISOFLEX-R



4-glove ETF ISOFLEX-R with hatch



4-glove ETF ISOFLEX-R with two hatches



Two 3-glove UDAF ISOFLEX-R with hatch in the middle



4-glove UDAF ISOFLEX-R with two hatches



# Accessories and options

## Getinge ISOFLEX-R Isolators

### Bio-decontamination alternatives

When it comes to bio-decontamination, the Getinge ISOFLEX-R provides the means to bio-decontaminate the isolator working chamber, the hatch, or both chamber and hatch simultaneously. The integrated H<sub>2</sub>O<sub>2</sub> generator ensures safe operations and reliable processes. The unit is controlled by the same interface as the isolator and provides full traceability of H<sub>2</sub>O<sub>2</sub> bottles.

### Integrated monitoring devices:

- H<sub>2</sub>O<sub>2</sub> sensors for operator safety
- Active air sampler
- Non viable particle
- Wireless Glove Leak Tester (GLT)

### 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

### Shelving solutions:

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

### Other typical accessories:

- Hanging bars with hooks
- Service plate with tri-clamp passthroughs and cable glands
- H<sub>2</sub>O<sub>2</sub> catalytic converters
- Integration of peristaltic pump for filtration
- Sleeve extenders with finger separators
- And many more accessories...

The optional ISOTURN transfer hatch provides fast bio-decontamination. A space-saving rotating door makes it possible to unload while reloading/bio-decontaminating another load.



Isoturn hatch before decontamination



Wireless Glove Leak Tester (GLT)

# 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 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 ISOTEST Isolator



## 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 ISOFLEX-S Isolator

### A transparent, flexible-wall isolator

The Getinge ISOFLEX-S isolator has transparent semi-rigid plastic walls that provide a panoramic view of the working area. Getinge 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





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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