Solutions for sterility testing

Isolators to secure contamination prevention to your process

GETINGE

Ensure reliable and safe testing

Avoid risk of sample contamination

Sample contamination during sterility testing is a major issue in the biopharmaceutical industry. Getinge isolators and patented DPTE® transfer systems provide a safe, sterile, self-contained environment for the most crucial steps of the testing process.

Your biopharmaceutical facility requires the highest quality outcomes from its production processes. Sample contamination can be a costly problem, resulting in false positive results that can require expensive investigation and rework. At Getinge, we understand your need for maximizing uptime and performance.

Our isolators help you to safeguard against microbial and particulate contamination that can influence active ingredients, excipient potency, or administered use of a drug in a way that can negatively affect patient health. Our ergonomic design, continous workflow, easy access, and fast bio-decontamination help increase productivity and efficiency.

Tailor-made isolator solutions

The basic principle of isolation technology is to separate a process from the environment. This can be achieved with two different solutions: a traditional grade B cleanroom with Laminar Flow Cabinet (LFC) or a more flexible solution such as an isolator. Getinge Isolators narrow containment to just around the process within the chambers. Our solutions minimize downtime and avoid contamination and false positives during sterility testing of sterile drugs, components, and medical devices.

Running costs are relatively low – sometimes as low as 20% of the costs of a cleanroom solution, as only the conditions inside the isolator need to be controlled. Either UniDirectional Air Flow (UDAF) or Engineered Turbulent Air Flow (ETF) can be applied, depending on your process needs or local regulations.

In an isolator system, standardized, pre-tested components are combined into a customized overall solution. Most of the technical solutions such as integrated H_2O_2 generator are common across the range. A modular isolator system provides flexible configuration and modification possibilities to meet your specific process and application requirements.

The industry standard for aseptic transfer

The transfer of material into and out of isolators requires specific technologies. Getinge La Calhène is the originator and manufacturer of the DPTE® solution, also known as Rapid Transfer Port (RTP) or Alpha-Beta transfer ports. This system is now the industry standard for transfer of aseptic or toxic products in biomedical research institutions and pharmaceutical factories all over the world.

Supporting regulatory compliance

To ensure safety, all Biopharmaceutical production facilities must comply with strict regulations. These include current Good Manufacturing Practices (cGMP) associated with production of the finished product, and current Good Laboratory Practices (cGLP) associated with quality testing related to the product. The components in an isolator system are pre-tested resulting in reliability at a very high level and facilitated validation of equipment. Each process and cycle must follow validated customer requirements to deliver stable and repeatable results in the shortest time and at a minimum cost. Getinge provides a fully documented on-site validation service to fulfill customer and regulatory requirements.

ISOFLEX-S Isolators

A transparent softwall isolator, providing 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. This solution is also known as semi rigid isolator.

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 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 solid, polished 316L stainless steel for easy and efficient cleaning and robstuness.

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) configuration 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, in order to increase 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.

ISOFLEX Isolators

A modular, rigid wall isolator with fast bio-decontamination solutions

ISOFLEX Isolators are ergonomic and easily upgraded to adapt to your changing needs. The large front window is easily opened with hydraulic assistance for fast loading. Inflatable seals made of FDA approved antibacterial silicone ensure leaktightness during bio-decontamination and processing.

Modular design for flexible use

A modular design allows the ISOFLEX Isolator to be tailored according to your specific needs. Three-glove or four-glove versions are available. Bio-decontamination airlocks can be added at one or both ends of the isolator.

Validated process control and traceability

ISOFLEX offers either a Siemens or Rockwell 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. 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. ISOFLEX is fully FDA 21 CFR Part 11 and GMP Annex 11 capable and compliant.

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.

ISOTEST Isolators

Double work station for increased productivity

The ISOTEST system design is optimized for sterility testing procedures. Two operators can have simultaneous access, allowing them to work with the same or different sterility testing methods inside the isolator.

The system can be used with any combination of closed or open membrane filtration, direct inoculation methods, and rapid microbiology methods (RMM).

Minimize downtime for improved throughput

Eliminate unproductive downtime between batches. The ISOTEST Isolator allows for a continuous testing process instead of a batch process. Short bio-decontamination cycles and the capacity for dual operations combine for a throughput rate of up to 40 tests per 8 hour shift.*

Effective bio-decontamination

The ISOTEST Isolator offers the possibility to bio-decontaminate the total volume of the unit; the hatch can be included, or bio-decontaminated separately. Bio-decontamination of the load within the hatch occurs quickly – often within 30-45 minutes.

The integrated bio-decontamination unit uses hydrogen peroxide (H_2O_2) vapor (HPV) as sterilant. The generator is controlled by the same PLC as the unit, providing reliable operations.

Validated process control and traceability

Both the isolator and integral bio-decontamination unit are controlled by a single Siemens PLC control system. The control system monitors and records process-critical reports that can be sent to a printer, remote PC (optional); or stored in the customer network through SCADA integration (optional).

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

* Based on an average test size of 20 ml containers / vials

ISOPRIME Isolators

Optimized for common aseptic applications

Versatile, the ISOPRIME is suitable for all major sterile applications from aseptic filling and repackaging of sterile components, to sterility testing, compounding, preparation of medical drugs and devices, and more.

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.

Two types of ventilation to maintain aseptic conditions

With the ISOPRIME, 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

ISOPRIME offers a Siemens PLC for process control and monitoring. The control system is equipped with a 10” color touch panel PC with an intuitive user interface for easy navigation, operation, and parameter monitoring. The reports are generated in PDF and can be transferred to a network server, a USB flash drive, or sent to a network printer.

User access is easily managed and adapted to your needs using a non-pyramidal structure. Authorized users can adjust process parameters according to the unique requirements of a specific process. The system allows you to choose up to two signatories.

ISOPRIME is FDA 21 CFR Part 11 compliant in accordance with the PLC capabilities.

Documentation, validation and process qualification

Be compliant

Save time and money along the validation chain. All stages of the manufacturing process are examined and documented, from the design specification through component selection, fabrication, assembly, and Factory Acceptance Testing (FAT).

Our documentation package ensures a strict quality control procedure in compliance with current Good Manufacturing Practice (GMP).

In-process checking

In-process checks ensure that only the specified materials and components are being used. During assembly, variety of inspections may be performed – e. g. leak and pressure testing, assembly operations, and control of surface finish when applicable.

Documentation

The documentation package can be used as an integral part of the gamp 5 qualification material. It includes installation and user manuals, validation support documentation, and technical manuals.

Factory Acceptance Testing (FAT)

Before installation, each product is tested according to a pre-agreed procedure. As an option, "pre-validation" of equipment can be performed at this stage: carrying out test procedures identical to the ones used for on-site validation. After installation, qualified technicians supervise the start-up and perform IQ/OQ/CD* during the Site Acceptance Test (SAT).

Qualification

Getinge validation team provides all-inclusive solutions for the qualification of equipment in accordance with all major international regulations. We also provide operator and technician training, tailored according to the application.

* Installation Qualification / Operational Qualification / Cycle Development

Accessories and options

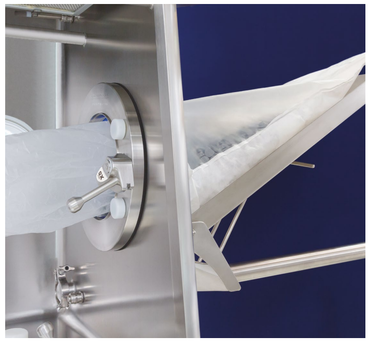
Common across Getinge's isolator range

- Fully FDA 21 CFR part 11 / Annex 11 compliant SCADA supervision (built-In or stand alone)
- Sleeve extenders with finger separators
- Gloves
- Hanging bars with hooks
- Shelvings, racks and baskets
- Service plate with tri-clamp passthroughs and cable glands
- H_2O_2 catalytic converters
- Integration of peristaltic pump for filtration
- H_2O_2 sensors including for operator safety
- Active air sampler
- Non-viable particle
- Glove leak tester (built-in or stand alone)
- and many more ...

Getinge provides customized accessories tailored to your needs depending on your application.

DPTE® transfer systems

Application-specific options for comfort and safety



The original rapid transfer port

Sterile transfer of components and other materials between sterile and non-sterile areas has always been a major concern in the pharmaceutical production industry. Originally developed for the safe transfer of waste in nuclear facilities,the DPTE® technology has been adopted as the industry standard for pharmaceutical production contamination. The core of the system is the DPTE® Alpha port with secure interlocks for totally safe connections and disconnections.

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. This solution is ideal for cytotoxic waste management.

Safe and sterile transfer of components and materials

DPTE® Beta Containers are used to bring in, remove, or transfer material from one environment to another, without breaking containment. Getinge produces a range of standard PE (HPV bio-decontamination or gamma irradiation) and stainless steel containers (HPV biodecontamination or steam sterilization), and also offers customized containers with specific baskets, drawers, and accessories.

Learn more on

The DPTE® System –
The Original Rapid Transfer Port

Click here to download the brochure

Getinge service and support

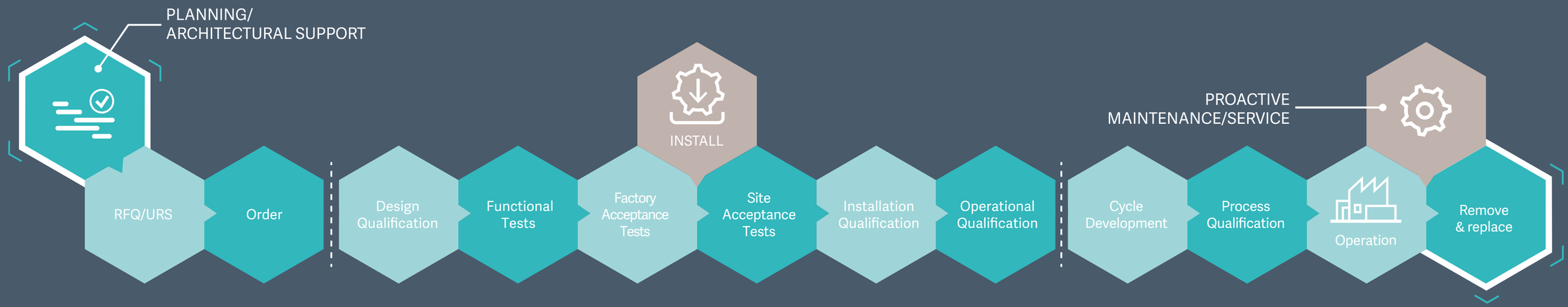
A service agreement with Getinge gives you peace of mind. Our global service network provides expert preventive, predictive and reactive maintenance to help you maximize uptime and safety – and to keep your operations running smoothly.

A good relationship is built on trust and we are committed to serving your needs wherever you are in the world. With our service team by your side, you are ready to meet the requirements of accrediting organizations and government regulatory agencies.

Our services include:

+ Calibration services
+ Upgrade packages
+ Operator and technician training
+ Process verification
+ Validation services

With you every step of the way



Our commitment goes far beyond supplying equipment. We support you with project planning and setting the right specifications and requirements.

Our experience in manufacturing, installation and commissioning allows us to manage the project from start to finish. When in operation, proactive maintenance secures your uptime. **In short – we are with you every step of the way.**

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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