Discover the new ISOFLEX-R™ from Getinge
In recent years, Getinge La Calhène has invested in R&D, microbiological laboratory space and Virtual Reality to innovate further and faster and thus develop new technologies to meet our customers’ constantly evolving needs.

In any sterile operation, maintaining the sterility of goods that are ready to use or require sterilization is a crucial task for which aseptic conditions are only one part of the requirement.

Getinge La Calhène developed a new generation of highly modular isolators to increase efficiency and speed of production, with improved ergonomics and maintenance.

Getinge’s ISOFLEX isolators are the answer to your sterile handling needs.

- Simple ISO 8 location
- Can also be in a non-classified room with restricted access for sterility testing, gowning is simple
- FDA 21 CFR part 11 compliance
- Security with validated sterility of the working area and cross-protection of product/operator/environment
- Traceability for all steps of the sterile handling process
- One single Siemens PLC controller and touchscreen display for repeatable, reliable operation to avoid errors and optimize productivity
- Validated process with integrated sterilizer reduces bio-decontamination cycle times
- Easy to install and operate
- Routine maintenance ensures compliance with USP 1116 for microbiological monitoring and ISO 14644 for non-viable particulates
- Cost-effective, modular and easy to upgrade
A wide range of **applications** in the pharmaceutical industry

**Isoflex isolators are used for numerous applications in the pharmaceutical industry,** where sterile, toxic and/or contaminated material has to be transferred without compromising containment.

- Sterility testing
- Clinical trials
- Filling
- R&D
- Sampling
- Weighing and dispensing
- Bulk transfer
- Addition of Ingredients
- Compounding
- Powder processing – milling, grinding, tumbling etc.
- Solid doses – tablets, capsules
- Highly Active Pharmaceutical Ingredients (HAPIs) handling
- Reconstitution of cytotoxic drugs
- Biomedical research (animal lab facilities)
- Parenteral Nutrition (TPN) compounding

_and many more..._
**ISOFLEX-S™**

Robustness and comfort

Getinge’s 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. Available in 3-glove and 4-glove versions.
Visibility
Tough PVC transparent walls on 4 sides give a panoramic view of the working area, its tools and components. The canopy made of 0.3 mm PVC film, can be disconnected as required.

Leaktightness
Automatic leaktesting procedure for the work area for high level protection of the operator and environment.

Mobility and modularity
Isoflex-S™ isolators are light-weight and mobile, fitted with castors to facilitate movement and connection to other isolators or filling lines using Getinge's patented DPTE® system. A 565 mm diameter door at each end, which can be replaced by the appropriate DPTE® systems (in option).

Cleanability
The 316L stainless steel base is easy to clean.
ISOFLEX-R™

A state-of-the-art new isolator

ISOFLEX-R™

modularity with no limit...

It is tailored to your specific needs, combines optimized ergonomics and efficiency with high-speed bio-decontamination solutions.

The only limit is your imagination.
Modular design
- Available in 3-glove and 4-glove versions
- Bio-decontamination airlock can be added (Isoturn or standard one)
- Unidirectional airflow or Turbulent Flow
- Wide range of options available

Higher ergonomics to work easily
- Large HMI screen with new features
- LED lighting
- Space-saving
- Safe and easy opening (front opening lift-up window)
- Easy installation of the products inside the isolator
- Retrofittable on site

Higher level of traceability to limit uncertainty
- Paperless chart recorder (in option)
- Camera (in option)
- Fully compliant with standards:
  - FDA
  - EU & US
  - CFR 21 part 11
  - GMP
  - GAMP5
- Integrated SCADA system (audit-trail, electronic signature, PDF printout generation...)

Risk elimination
- Secure opening of front window
- Double HEPA filtration (in option)
- Stand-alone or integrated Glove Leak Tester
- FDA approved anti-bacterial inflatable seals
- Compatible with our full range of DPTE® solutions to assure 100% leaktightness

Various high-speed bio-decontamination solutions to work faster
- ISOTURN™, standard airlock, H₂O₂, BIOTRACE Noxilizer Inside...— see page 9
Time-saving and faster than any other, ISOTURN does it in 10 min!

Getinge’s fast bio-decontamination transfer airlocks for the ISOFLEX-R™ help to increase productivity

ISOTURN™ quick transfer solution

• Unloading in workstation while re-loading / bio-decontaminating another load!
• Space-saving rotating door
• Flash bio-decontamination (10 min)
• Small volume airlock: equivalent to 2 kits for sterility tests by filtration
• Modular racking / transfer solution

Patented ISOTURN™ space-saving rotating door
space-saving bio-decontamination devices

3 bio-decontamination possibilities with new airlocks:

- Isolator working chamber only
- Transfer airlock volume only
- Both chambers together

Integrated STERITRACE H₂O₂ sterilizer
- Cost-effective and reliable with no additional equipment to manipulate and maintain
- Only one user interface to control both isolator and sterilizer H₂O₂
- Safe easy manipulation, high level security
- No odor, no residue
- Fully traceable: batch number, expiry date
- RFID chip

BIOTRACE Noxilizer Inside

BIOTRACE Noxilizer Inside is a bio-decontamination system using Nitrogen Dioxide (NO₂). Its unique “On Demand” technology generates Nitrogen Dioxide as needed. Residual levels may be reduced to 100 part-per-billion levels, a valuable feature for sensitive drug products, e.g. biologics.

- Fast cycle times (halved)
- Low residuals
- Safe and simple to use
- Room / ambient temperature process
- Compatible with a wide range of materials including sensitive electronic devices
- Aeration by ventilation via scrubber module
- Gas concentration sensors for real time process monitoring

Modular design
- Humidification and delivery system is integrated with the isolator to be bio-decontaminated
- Control system is integrated with the isolator control system
A “one-size-fits-all” isolator that goes anywhere

Compact footprint for easy installation

Space-saving
• Modular
• Can be disassembled easily
• Bio-decontamination airlock(s) can be added at a later stage

Easy maintenance
• Turbulent flow filters are safely changeable from the inside without breaking containment
• UDAF ceiling filters can be reached from front or right hand side with a quick locking system with eccentrics
• Sensor transmitters are easily reachable for calibration
• Extra filter option for cytotoxic applications: additional filtration (safe change) prior to air recirculation

Removable castors for easy handling

*Can pass through a 800mm x 2000mm wide corridor
Compatible with our whole range of DPTE®

Although placing a physical barrier between the process and the user provides significant safety and contamination control benefits, it also introduces operative challenges: how to move material into and out of an isolator without breaking the sterile containment? Both ISOFLEX-R™ and ISOFLEX-S are compatible with our full range of DPTE® solutions to assure ultra-clean transfer in a great variety of applications.

- DPTE®-xo and DPTE®-xs transfer ports
- DPTE-BetaBag® range
- DPTE® Beta containers: plastic and stainless steel (autoclavable)
- Single Use Liquid transfer solutions
Getinge Group is a leading global provider of products and systems that contribute to quality enhancement and cost efficiency within healthcare and life sciences. We operate under the three brands of ArjoHuntleigh, Getinge and Maquet. ArjoHuntleigh focuses on patient mobility and wound management solutions. Getinge provides solutions for infection control within healthcare and contamination prevention within life sciences. Maquet specializes in solutions, therapies and products for surgical interventions, interventional cardiology and intensive care.