

CUSTOMER:

REFERENCE:

SOFT WALL GLOVE ISOLATOR Transfer isolator

SPECIFICATION

PRODUCT SPECIFICATION

The transfer isolators (SWB) are leaktight enclosures equipped with means of transfer and manipulation which keep enclosed environment allowing a cross protection operator/product against microbiological and chemical contaminations without compromising the environment.

APPLICATION

Transfer isolator allows to bio decontaminate safely loads of product and components before to introduce them in aseptic processing areas.

KEY FEATURES

- 316L stainless steel base,
- Transparent flexible PVC canopy (0,3 mm thickness), with viewing windows,
- 304 L stainless steel welded supporting frame on lockable casters,
- Ventilation system capable of more than 20 air changes per hour, and positive pressure of 40 ± 10 Pa (adjustable),
- Control system:
 - Manual command with automatic pressure control "PARIS 1" type,
 - Full automatic control command PLC system (Siemens),
- Single inlet and outlet HEPA filters,
- Manipulation by gloves mounted on sleeves (changeable without breaking the sterility) with sleeve support for bio decontamination (option),
- Transfer systems using Beta part of DPTE® double door systems and conventional doors,

QUALITY STATEMENT

Confidence in the Getinge group is the most important quality criteria. This must be the hallmark of all our external and internal commitments, activities and products. Products and services supplied by Getinge must conform to the agreed terms and expectations to ensure recommendations for further business. The achievement of these quality goals is the basis for continued competitive and successful enterprise.



STANDARDS & CODES

The Transfer isolators comply with all appropriate standards, codes and directives relevant to the region of installation. The equipment is manufactured according to industry requirements and standards. A declaration this matter is available on request.

Electrical regulations

- Directive n° 89/336/EEC amended 92/31/EEC,
- Directive n° 73/23/EEC.

Glove regulations

- Directive n° 89/686/EEC.

Automation regulation

- GAMP4 procedures, 21CFR Part 11 and current guidelines are followed in all our documentation and validation support materials.
- 21CFR Part 11 compliant in accordance to the PLC capabilities.

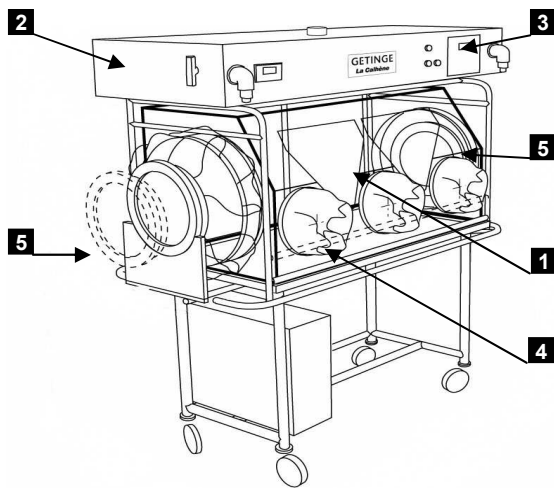
-
- ☐ - Denotes optional feature - Check box as required.
 - Commercial specifications only.
 - Pictures and drawings non contractual.

DESCRIPTION

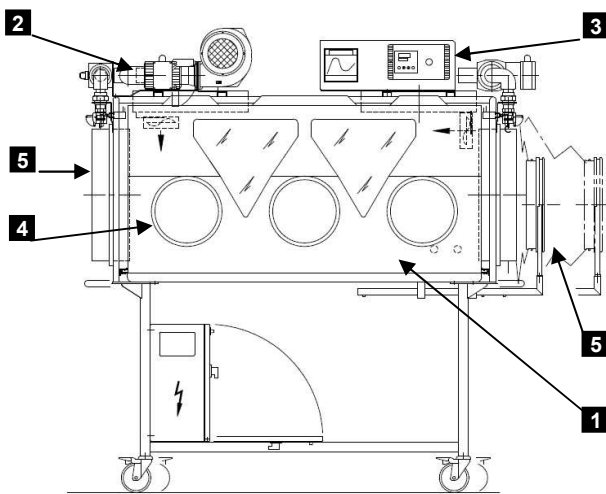
PRODUCT DESCRIPTION

The transfer isolator is composed of 5 parts:

- Containment enclosure **1**
- Ventilation / filtration **2**
- Control system **3**
- Manipulation system **4**
- Transfer system **5**



In this picture, a transfer isolator with PLC control system.



In this picture, a transfer isolator with "PARIS 1" control system.

PRINCIPLE OF OPERATION

All the surfaces and the atmosphere of a transfer isolator can be biodecontaminated using a chemical process (either using hydrogen peroxide or peracetic acid).

The transfer isolator, mobile enclosure, can be connected to a work station (with gloves or half-suit), using a leak tight transfer system (DPTE®).

The operator can operate inside the sterile environment using manipulation systems while remaining outside.

BASIC DESIGN FEATURES

Design features and material definition conform to the specification listed below, unless specifically mentioned as optional.

Containment enclosure

It comprises three main parts:

- A stainless steel base,
- A stainless steel welded structure,
- A transparent flexible PVC canopy.

Stainless steel base

The base is constructed from solid, high quality, stainless steel (type 316L or European equivalent).

Surfaces are polished to facilitate cleaning (Ra 0,5 µm in accordance with ISO 1302 norm).

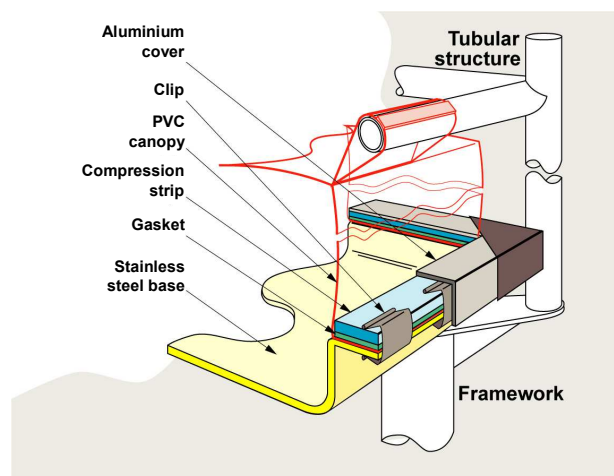
Stainless steel welded structure

Frame and structure are constructed from solid, high quality, stainless steel (type 304L or European equivalent).

Surfaces are polished to facilitate cleaning (Ra 0,8 µm in accordance with ISO 1302 norm except for weldings).

Transparent flexible PVC canopy

The canopy is manufactured of transparent flexible PVC (polyvinyl chloride) of 0,3 mm thickness, with viewing windows, attached on the stainless steel base.



Ventilation / filtration with "PARIS 1" type regulation

It comprises two modules (Air inlet and outlet modules):

Air inlet module (inlet air) with:

- Inlet pre-filter,
- Inlet air blower G2D 160 (air flow rate),
- DN 50 isolation valve in PVC,
- Stainless steel filter housing with pass-through for Emery testing,
- 99,995% MPPS HEPA filter 3P3.

Accessories for hydrogen peroxide H₂O₂

- DN 40 sterilizing agent inlet valve in PVC,
- Circulation fans for good distribution,

Accessories for peracetic acid PA

- One inlet PA.

Air outlet module (extraction) with:

- 99,995% MPPS HEPA filter 3P3,
- Stainless steel filter housing with pass-through for Emery testing,
- DN 50 isolation valve in PVC,
- Flexible pipe 60mm, 5 meter long.

Accessories for hydrogen peroxide H₂O₂

- DN 40 sterilizing agent outlet valve in PVC,

Accessories for peracetic acid PA

- Sterilizing agent outlet by-pass valve in PVC.

Ventilation / filtration with PLC type regulation

It comprises two modules (Air inlet and outlet modules):

Air inlet module (inlet air) with:

- Inlet pre-filter,
- Inlet air blower G2D 120 (air flow rate),
- Motorized DN 80 isolation valve in PVC,
- Stainless steel filter housing with pass-through for Emery testing,
- 99,995% MPPS HEPA filter 3P3,
- Motorized DN 40 sterilizing agent inlet valve in PVC, for hydrogen peroxide H₂O₂ and peracetic acid.

Accessories for hydrogen peroxide H₂O₂

- Circulation fans for good distribution.

Air outlet module (extraction) with:

- 99,995% MPPS HEPA filter 3P3,
- Stainless steel filter housing with pass-through for Emery testing,
- Motorized DN 80 isolation valve in PVC,
- Extraction air blower G2D 120 (pressure),
- Flexible pipe 90mm, 5 meter long.

Accessories for hydrogen peroxide H₂O₂

- Motorized DN 40 sterilizing agent outlet valve in PVC,

- Solenoid valve for pressure tapping,

Accessories for peracetic acid PA

- Motorized DN 20 sterilizing agent by-pass valve in PVC.

Control system

Manuel command with automatic pressure control PARIS 1:

- Adjustment of the set pressure,
- Display of the measure of the pressure,
- Parameters of high and low thresholds of pressure supervision with audible and visual alarms,

Full automatic control command PLC system:

PLC and operator interface:

- Full automatic leak test before sterilisation or during production,
- Automatic transition between phases,
- Phases parameters adjustable,
- Status, alarms and measurements displaying,
- Access control by password,
- Automatic phase report,
- VHP® full automatic control command by isolator (parameters and report only for integrated VHP® M100S).

Printer:

- Report print out,
- Date – time – start – end of each phase,
- Pressure data max – min – scale – temperature,
- VHP® sterilisation report (only for integrated VHP® M100S).

Manipulation system

Manipulation inside the isolator is done through glove-sleeve assemblies. Gloves are available in various sizes and various materials such as neoprene, Hypalon or neoprene / Hypalon double dipping. The sleeves are made of Hypalon (*various materials available*).

The standard is:

- Hypalon sleeve,
- Ready to fit - Glove Neoprene (T7 size).

Ready to fit Gloves

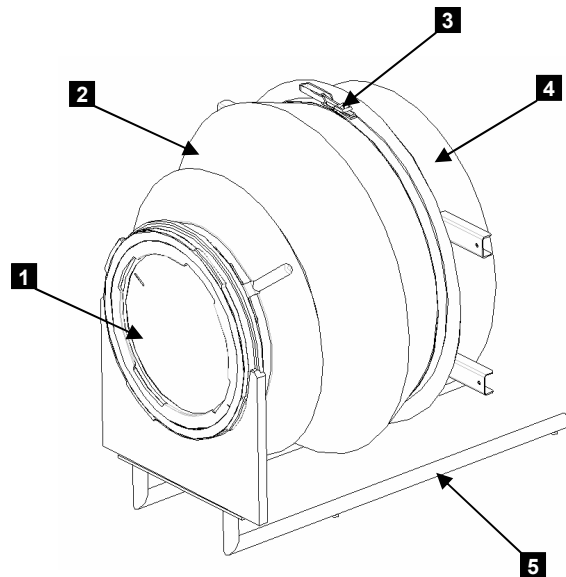
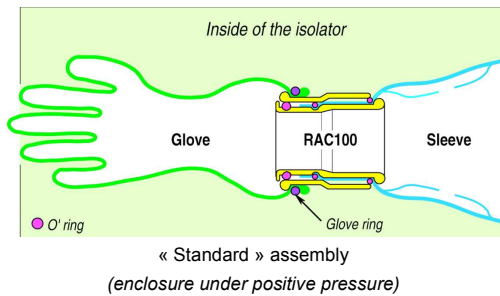
Particle free & sterile ELS gloves in individual packaging.

The shape of the ELS glove has been specifically designed to work in isolator allowing a glove interchange without breaking the leaktightness of the isolator.

The "Ready to fit" ELS Glove provides improvement for better use in a sterile isolator:

- Double rotor-cleaning and drying in an ISO class 5 room to eliminate the particles,
- Individual double packaging,
- Beta beam sterilization with a Sterility Assurance Level (SAL) greater than 10⁻⁶ according to the European Pharmacopoeia (EP) 4th edition § 2.6.1,
- Identification with a batch number and expiration date.

The assembly of the glove onto the sleeve is done using a cuff ring called RAC100, which is used to test the integrity of the glove using the GLT (*Glove Leak Tester*) and for replacement of the glove without breaking the sterility. Gloves supplied by GETINGE-La Calhène are EC certified.



Transfer system (DPTE® beta assembly)

DPTE® BETA mounted on a sliding support for the connection with another isolator.

It comprises five main parts:

- DPTE® beta part **1**
- Transfer sleeve **2**
- Clamp collar **3**
- Ø 565 door **4**
- Sliding support **5**

DPTE® beta part:

The beta flange and beta door are made of high molecular weight HDPE.

A J3L E lip seal made of PVC (polyvinyl choride) is mounted onto the beta flange.

Transfer sleeve:

The transfer sleeve is manufactured of transparent flexible PVC (polyvinyl choride) of 0,3 mm thickness, and allows the connexion (by rotation) of beta part onto the DPTE® alpha part.

Clamp collar:

The clamp collar is manufactured from solid, high quality, stainless steel (type 304L or European equivalent).

Ø 565 door:

The Ø 565 door is manufactured from solid, high quality, stainless steel (type 316L or European equivalent).

Sliding support:

The guides are manufactured of high molecular weight HDPE, and the support is constructed from solid, high quality, stainless steel (type 304L or European equivalent).

Transfer system (conventional door)

The conventional door allows to load or unload easily the isolator.

It comprises three main parts:

- Ø 565 door **1**
- Clamp collar **2**
- Cap **3**

Ø 565 door:

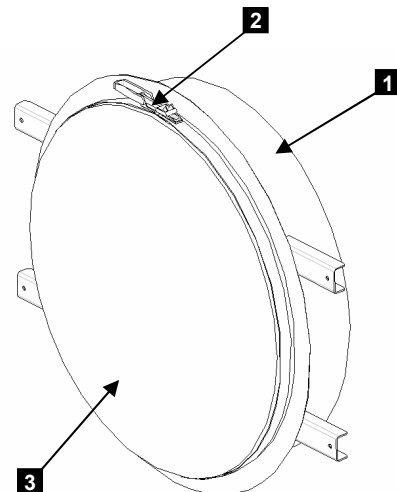
The Ø 565 door is manufactured from solid, high quality, stainless steel (type 316L or European equivalent).

Clamp collar:

The clamp collar is manufactured from solid, high quality, stainless steel (type 304L or European equivalent).

Cap:

The cap is manufactured of transparent flexible PVC (polyvinyl choride) of 0,3 mm thickness.



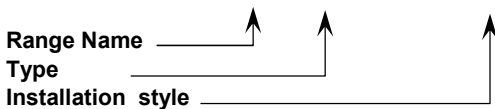
ORDERING

ORDERING

Description

Use the description below in combination with the capacity table to select the appropriate models.

Example Model: **ISO SWB T 3 GTS PLC VHP® A F**



INSTALLATION STYLE SELECTION

Containment enclosure (canopy)

3 Gloves (3 GTS)

4 Gloves (4 GTS)

Control system

PARIS 1

PLC

Sterilizer interface

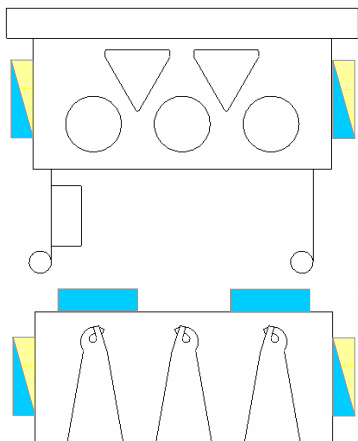
hydrogen peroxide H₂O₂ – integrated VHP® M100S

hydrogen peroxide H₂O₂ – mobil VHP® M100S

hydrogen peroxide H₂O₂ – mobil VHP® 1000ED

Peracetic acid PA - MAN

Transfer system



DPTE® beta assembly

Ø 270 DPTE® beta

Ø 350 DPTE® beta

Right hand side (A)

Left hand side (B)

Right backward hand side (C)

Left backward hand side (D)

Conventional door

Right hand side (E)

Left hand side (F)

Manipulation system

Hypalon sleeve

Ready to fit - Glove Neoprene (T7 size)

DIMENSIONS

(Diagrams or tables)

Transfer isolator	DPTE® beta assembly retracted w x h x d (mm)	Internal dimension for containment enclosure w x h x d (mm)
ISO SWB T 3 GTS A F	1950 x 2020 x 825	1500 x 750 x 680
ISO SWB T 3 GTS C or D and E or F	1900 x 2020 x 1000	1500 x 750 x 680
ISO SWB T 4 GTS A F	2440 x 2020 x 825	2000 x 750 x 680
ISO SWB T 4 GTS C or D and E or F	2370 x 2020 x 1000	2000 x 750 x 680

OPTION LIST (Detail see page 6)

Containment enclosure

1" ½ extraction drain on base

2 Hanging bars with hooks

Perforated shelves (600 x 208 mm 3 levels)

Lath floor

Serving hatch

Ventilation / filtration

Extraction air blower G2D 160 (for "PARIS 1" type only)

Control system

Temperature probe (for "PARIS 1" type only), included in PLC

Drager probe H₂O₂ – 0 ppm / 5 ppm -operator protect

Drager probe H₂O₂ – 0 ppm / 50 ppm -residual monitoring

Drager probe H₂O₂ – 0 ppm / 2000 ppm-sterilisation monitoring

Digital recorder

Paper recorder

Lighting (for "PARIS 1" type only), included in PLC

Stainless steel electrical cabinet (type 316L or European equivalent).

Safety power

Autotransformer

Other voltages:

Manipulation system

Sleeves support for sterilization

Swivelling armrest

Sleeve - PVC / DIVETEX

- Ready to fit Glove – Neoprene

Size	3/10	5/10
T7	<input type="checkbox"/>	Standard

- Neoprene glove

Size	3/10
T7	<input type="checkbox"/>
T8	<input type="checkbox"/>
T9	<input type="checkbox"/>

- Neoprene / Hypalon glove

Size	5/10
T7	<input type="checkbox"/>
T8	<input type="checkbox"/>
T9	<input type="checkbox"/>

- Hypalon glove

Size	3/10
T7	<input type="checkbox"/>
T8	<input type="checkbox"/>
T9	<input type="checkbox"/>

Transfer system (conventional door)

- Ø 565 door HDPE (for “PARIS 1” type only)

PROCESS FEATURES AND OPTIONS

1” ½ extraction drain on base

The 1” ½ extraction drain makes possible to evacuate the liquids.

Hanging bars with 12 hooks (x2)

The Hanging bars with hooks are manufactured of stainless steel (type 316L). It allows hanging up loads.

Perforated shelves (600 x 208 mm)

The 3 level perforated shelves is manufactured of stainless steel (type 316L). It allows installing loads in the isolator in order to optimize their bio-decontamination.

Lath floor

The lath floor is manufactured of stainless steel. It allows installing loads on the base in order to optimize their bio-decontamination.

Serving hatch

The serving hatch is manufactured of stainless steel (type 316L). It allows transferring easily the loads from the transfer isolator to the working unit.

Safety power

The safety power allows maintaining into functional phase the isolator during an electric power cut-off. “Uninterruptible Power Supply” (UPS).

Autotransformer

- Getinge-La Calhène can supply an autotransformer for other voltages than 230V,
- The isolator must be connected using a 2P+T standard power outlet connected to earth and protected against excess currents.

Manipulation system

Sleeves support for bio-decontamination.

The sleeves support optimize their positioning during the phase (limit hidden surfaces). This device also inhibits the introduction of the hand in the isolator during the sterilization phase.

Transfer system (conventional door)

The Ø 565 door can be manufactured of high molecular weight HDPE instead of 316L.

SERVICES

Check

Standard:

The Transfer isolator is inspected before shipment. This operation is carried out by our Inspection Quality Department following the inspection plan.

The inspection plan describes the manufacturing process and Inspection. It gives the input and output datas of the different phases of the product manufacturing and inspection.

Inspection sheets are signed by the Inspection Quality Department and the Quality Internal Validation Department.

Option:

FAT the validation protocol (Factory Acceptance Test), written according to GETINGE-La Calhène format and test procedures. The protocol is send to the customer for approval before execution test.

Documentation

Standard:

- English language
- French language
- Operating file including (following general goods-in acceptance testing procedure):
 - General description (Piping Instrumentation Diagram),
 - Assembly drawing(s) and parts list(s),
 - Electrical file(s),
 - Technical documents (component data sheet),
 - User manual(s),
 - Inspection notes,
 - Certificates (material certificate main parts and the calibration certificates of the equipment used during the test),
 - Acceptance reports.

Option list:

- Other language:
- Factory Acceptance Testing (included the standard documentation in place of the inspection notes).
- Software package (for PLC only)
 - Detail Design Specification (DDS),
 - Software validation package.

PACKING AND OPTIONS

Packaging identification

- Item reference,
- Quantity,
- Assembly.

Packing method

- The Transfer isolator will be packed according to the agreed kind of shipment.

Storage conditions

- Normal storage temperature (16°C and 24°C).

SHIPPING AND OPTIONS

- Shipping by air,
- Shipping by sea,
- Shipping by road (distribution service),
- Shipping by road (direct carriage).

INSTALLATIONS

Limits of use / specification

- Operating pressure (*production*):
+40 Pa ± 10 Pa.
- Operating pressure (*bio-decontamination*):
+60 Pa ± 10 Pa.
- Temperature (*production*):
Between 16°C and 24°C.
- Temperature (*bio-decontamination*):
Between 18°C and 45°C.
- Climatic resistance:
20 to 70 % relative humidity without condensation.
- Environment classification at rest:
M 3.5 as per standard FS 209 E or Iso 5 as per standard ISO 14644-1.
- Inlet air change rate:
20 minimum per hour (*free extraction new filters*).
- Leaktightness specifications (*value ex-works*) :
0.1 % vol/h at 100 Pa.
- Filtration level:
≥ 99,995 % (*MPPS efficiency*).
- Equivalent sound pressure:
≤ 75 dBa.
- Type of flow:
Turbulent flow.
- Volume of the isolator (Values given for information only):
3 glove isolator:0.75 m³,
4 glove isolator:0.9 m³.

- Isolator protection index:
IP 20.

- Maximum load admissible:

Transfer isolator	ISO SWB T 3 GTS	ISO SWB T 4 GTS
LOAD (kg/m ²)	80 kg/m ²	90 kg/m ²

Operating limits

- Temperature range:
0°C / + 50°C.
- Maximum mechanical load:
- 50 Pa / + 200 Pa.

Electrical

- Power supply:
AC 170 to 264 V, 48 to 63 Hz.
- Number of phases:
1/2.
- Amperage:
5 A.
- Power:
1150 VA.
- State of compatible neutral:
IT, TT, TN.
- Breaking power:
State of ITneutral; 10KA.
State of TT / TN neutral; 20 kA.
- Testing voltage (*standard test*):
As per EN 61 010-1, 1995 issue,
Classification of II excess-voltage, degree of pollution 2,
- Electrical safety device:
As per EN 61 010-1, 1995 issue.
- Electromagnetic compatibility:
EN 50 081-2, 1992 issue,
EN 50 082-2, 1995 issue,
EN 61000-4-3, 1997 issue,
EN 61000-4-6, 1997 issue,
EN 61000-4-4, 1995 issue,
EN 61000-4-2, 1995 issue,
EN 55011, 1991 issue.

UTILITY REQUIREMENTS

Characteristics of the isolator room

- Recommended air change rate per hour: 5 minimum.
- Independent rejection of the sterilizing agent to the building for each isolator.

Transfer isolator

- Mains plug: 230V / 16A,

Sterilizer

VHP® M100S or 1000ED (hydrogen peroxide H₂O₂):

- Detector of hydrogen peroxide (H₂O₂),
- Evacuation for the regeneration phase,
- Mains plug: 230V / 50Hz / 20 A,

MAN (Peracetic acid PA):

- Medical quality compressed air set at 3 bars minimum.
- Mains plug: 230V / 50Hz / 1A,

ACCESSORIES

List of spare parts

Description	Part number
24 V indicator light (yellow)	19750
24 V leatight buzzer	19751
Adhesive for flexible PVC and vinyl	2884C
Beta door Ø 270 made of high density polyethylene	158C
Beta door Ø 350 made of high density polyethylene	1111C
Canopy	Depending of option (refer to its n°)
Cap for 565 door	6593C
Clamping band made of stainless steel Ø 450 (filter housing)	639C
Clamping band made of stainless steel Ø 565	6322C
HEPA filter 300 x 300 mm	6603C
Indicator cloth	6294C
J3L 270 E PVC for DPTE® beta flange 270	395C
J3L 350 E PVC for DPTE® beta flange 350	400C
Kit for replacing the J3L lipseal including one device for replacing the J3L lipseal, procedure of replacement, particle-free cleaning paper and silicone bottle	23024C
Membrane filter 0,2 µm	6599
Position switch	19721
Prefilter PRV160 for PARIS1	4643C

Pre-perforated stopper	2895
PVC cape for Ø 565 - 30/100	6593C
R48 O' ring (for RAC 100)	2285C
R77 O' ring (for RAC 300)	4177C
Reels of thermal paper of the printer	21160
Repair kit for canopy	630C
Rubber band in neoprene ES 450	6629C
Rubber band in neoprene ES 565	6630C
TLD 18/840 lamp	16918
Translucent 30/100 PVC transfer sleeve 565 door / beta flange 270	7485C
Translucent 30/100 PVC transfer sleeve 565 door / beta flange 350	7487C

RELATED & OTHER APPROPRIATE PRODUCTS DESCRIPTION

Depending on the application, the glove isolators can be used as:

Transfer isolator

- To sterilize the equipment, which is to be introduced into the work station isolator.

Work station isolator

- Where operations such as sterility testing, preparation of the product, ..., are carried out.



In this picture, a Work station isolator.

GLT

The glove in an isolator constitutes the weakest link in the containment barrier. GLT system allows "in situ" glove testing without breaking the absolute barrier and thereby stopping the exploitation.

Simple and rapid to operate (approximately 6 minutes to test one glove), the equipment is capable of detecting a glove perforation not visible to the naked eye (detect Ø 40 µm pin hole).

The standard equipment is designed for use with GETINGE La Calhène glove cuff ring system (type RAC 100).



In this picture, a GLT.



In this picture, a vapor generator for peracetic acid PA (MAN)

Bio-decontamination of an isolator

One of main characteristics of an isolator system is its capability to be bio-decontaminated and to keep a germ-free environment whatever operation or transfer performed. Even, in some application, the isolator is bio-decontaminated after process, in order to eliminate potential biohazard.

Bio-decontamination of an isolator is performed by contact of a gas or vapor form sterilant, generated by a stand-alone or integrated device. Getinge-la Calhène has experience with several suppliers.

All isolator for aseptic and bio-hazard operation are equipped with connections and for either bio-decontamination device selected.

Getinge-la Calhène has participated to development and integration of multiple bio-decontamination systems. Some have been developed for specific applications, like bio-decontamination with cycles of large filling isolator suites.

Bio-decontamination can be obtained from various chemical sterilants.

There are 2 main types of apparatus:

- Vapor generator for hydrogen peroxide H₂O₂ (VHP®),
- Vapor generator for peracetic acid PA (MAN),



In this picture, a vapor generator for hydrogen peroxide H₂O₂ (VHP®)

GLOSSARY

Transfer isolator: Leak tight volume used for the sterilization and the transfer of a work load.

Work station isolator: Leak tight volume used for the operations such as sterility testing, preparation of the product, ... are carried out.

SWB type: Isolators with transparent soft wall canopy, with a stainless steel base (SWB).

VHP® M 100S: Sterilizer using hydrogen peroxide (H₂O₂) in closed loop.

VHP® 1000ED: Sterilizer using hydrogen peroxide (H₂O₂) in closed loop.

MAN: Sterilizer using Soproper in open loop

Open loop: The sterilizer ensures the inlet of the sterilizing agent, the isolator extraction system ensures the outlet.

Closed loop: The sterilizer ensures the inlet and outlet of the sterilizing agent in the enclosure.

Hypalon: Synthetic elastomer compatible with H₂O₂.

Divetex: PVC coated material specially adapted to be used with an isolator.

DPTE® BETA: Container flange / container door / container body assembly. Moving part of the DPTE® system (for example a container).



Getinge provides complete solutions for effective and efficient cleaning, disinfection and sterilization in the healthcare and life science sectors. Our know-how comprises everything from architectural planning, production and handling equipment, to systems for full traceability of sterile goods. Our commitment covers expert advice, training and long-term technical support.

GETINGE

Getinge Infection Control
PO Box 69, SE-310 44 Getinge, Sweden
Phone: +46 35 15 55 78
Fax: +46 35 549 52
Info@getinge.com www.getinge.com

GETINGE

THE GETINGE GROUP is a leading global provider of equipment and systems that contribute to quality enhancement and cost efficiency within healthcare and life sciences. Equipment, services and technologies are supplied under the brands **ARJO** for patient hygiene, patient handling and wound care, **GETINGE** for infection control and prevention within healthcare and life science and **MAQUET** for surgical workplaces, cardiopulmonary and critical care.