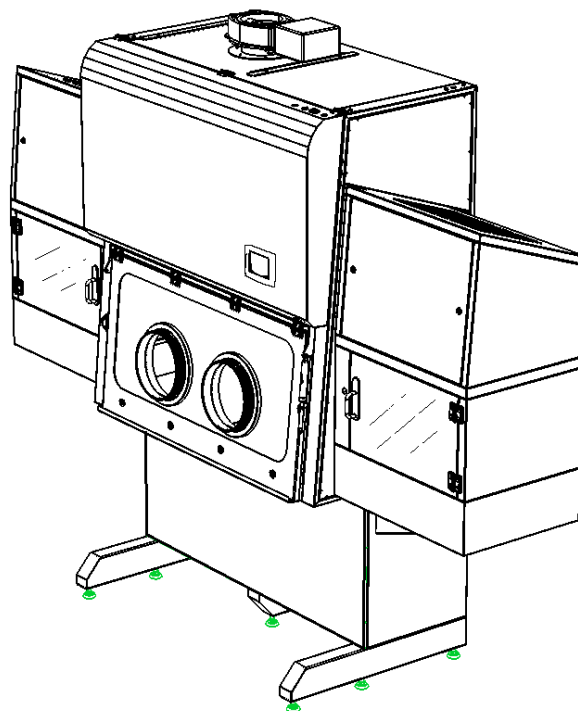


BIOAIR

ISOLATION TECHNOLOGY

ISOMATE



Summary

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1 DESCRIPTION

ISOMATE Cyto is a negative pressure isolator, designed to provide protection to operators, environment and products during processes requiring the manipulation of cytotoxic and mutagen (CMR) substances.

Operator and environment protection is achieved via a sealed work area with an inner pressure lower than the surrounding environment; the only access to the work area, when in operation, is through the lateral pass-boxes.

Products inside the working chamber are manipulated using the gloves installed on the front window.

The inner chamber is provided with a laminar flow of HEPA H14 filtered sterile air.

The pass-boxes are provided with a turbulent air flow of HEPA H14 filtered air.

An additional set of HEPA filters below the working surface collects all the CMR contaminated aerosols preventing them to reach the non-cleanable surfaces in the technical areas of the isolator (plenum, airflow channels, main and exhaust filters).

Two centrifugal motorblowers maintain the correct airflows and pressure gradients.

All internal surfaces are built in AISI316 stainless-steel.

2 GUIDE LINES & REFERENCE NORMATIVES

| Rif | Standard | Description |
|-----|----------------|--|
| [A] | ISO 14644-1 | Cleanrooms and associated controlled environments |
| [B] | ISO 14644-7 | Separative devices |
| [C] | EU GMP | EudraLex Good manufacturing practice |
| [D] | EN 1822-1 | High Efficiency Air Filters |
| [E] | CEI EN 61010-1 | Safety requirements for electrical equipment for measurement, control and laboratory use. Part 1: General requirements |
| [F] | 2006/42/CE | Machine Directive |
| [G] | 2014/30/UE | Electromagnetic compatibility (EMC) Directive |
| [H] | ISO 10648-2 | Containment enclosures — Part 2: Classification according to leak tightness and associated checking methods |
| [I] | DIN19280:2017 | Laboratory installations - Safety cabinets and glove boxes for cytotoxic substances and other CMR drugs |

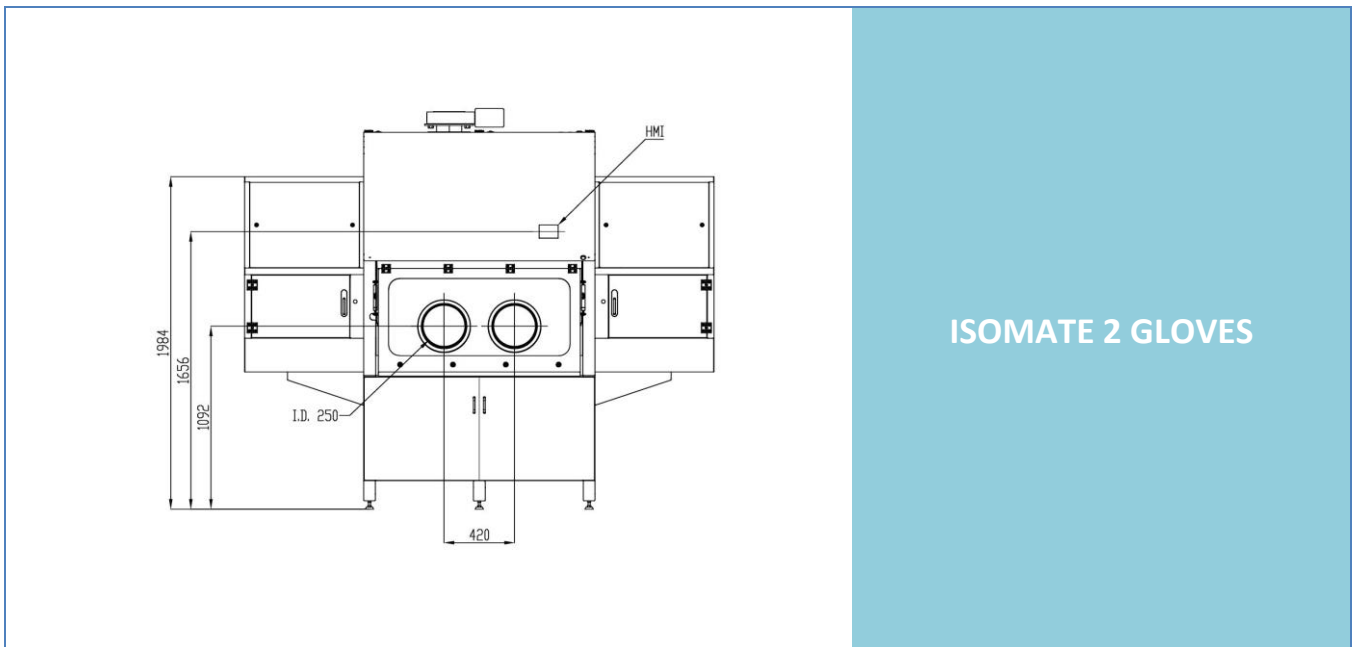
3 MAIN SPECIFICATIONS

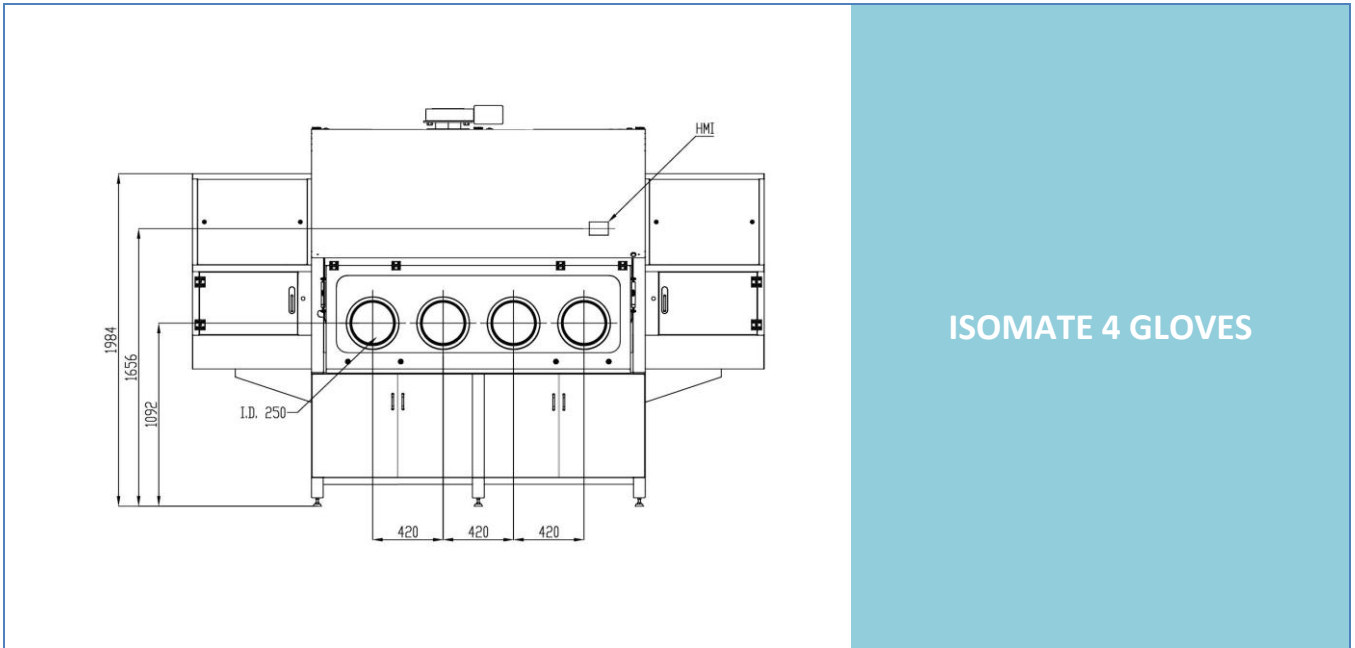
- Inlet air filter: HEPA H14 efficienza 99,995 MPPS (particelle 0,12 – 0,24 μm), \geq 99,999 DOP (0,3 μm).
- Main chamber downflow filter: HEPA H14 efficienza 99,995 MPPS (particelle 0,12 – 0,24 μm), \geq 99,999 DOP (0,3 μm).
- Exhaust air filters on each passbox: HEPA H14 efficienza 99,995 MPPS (particelle 0,12 – 0,24 μm), \geq 99,999 DOP (0,3 μm)
- First filtering stage (recirculated air, below work surface) with bag-in/bag-out filter removal system;
- Two (2) interlocked pass-boxes, with turbulent air-flow, more than 500 air changes per hour and an inner pressure between -30Pa and -50Pa with respect to the external environment (+25Pa and + 45Pa with respect to inner working chamber); cleanliness level ISO5 (EN14644-1);
- Dynamic air-barrier when opening the passbox inner door: the differential pressure creates a slight airflow toward the inner chamber avoiding contaminants to leave the working space. The air barrier is created by ad-hoc slots which prevent the contamination of the working area as well;
- Both passboxes are equipped with a manual sliding tray and tempered glass doors to allow entrance and exit of the products from two different sides;
- Inner chamber cleanliness classification: ISO 3 according to ISO 14644-1
- Leak tightness class 4 according to ISO 10648-2
- Automatic regulation of the positive pressure gradient inside the working chamber.
- Automatic regulation of the motorblower rotational speed to ensure constant air volumes and air flows and compensate for progressive filter clogging.
- Inner working area fully made of stainless-steel AISI316 with Scotch Brite® finish.
- External surfaces in epoxy powder painted cold-rolled steel S275JR.
- UV-C germicidal lamp on inner chamber backwall.
- 2 auxiliary power sockets inside the working chamber.
- Front window in safety multilayer glass.
- Round gloves flanges \varnothing 250 (2 or 4)

- Pass-box doors are interlocked. Pass-boxes are provided with a sliding tray for easier loading/unloading of products in the working chamber.
- PLC based control system.
- Full colour touch-screen control interface with graphical UI.
- Working chamber lighting provided by LED lamps.
- Semi-automatic leak-tightness test system (fully automatic test available as an option).

4 STANDARD SIZES

| | 2 GLOVES | 4 GLOVES |
|------------------------------|-------------------------|-------------------------|
| External Size - mm | 2.798 x 841 x 2.390h mm | 3.408 x 841 x 2.390h mm |
| Inner working area size - mm | 1.228 x 590 x 690h mm | 1.838 x 590 x 690h mm |
| Pass-box | 2 | 2 |
| HEPA filters | 4 | 4 |
| Motorblowers | 2 | 3 |
| Gloves | 2 | 4 |
| Working area classification | ISO 3 | ISO 3 |
| Power supply | 230V-50 Hz | 230V-50 Hz |





ISOMATE 4 GLOVES

5 AVAILABLE OPTIONS

- IV bar with hooks
- Camlocks to connect to an external VHP generator
- Fully automated leak test system
- Integrated hydrogen peroxide vapours generator (VHP)
- Particle monitoring system (in working chamber)
- Microbiological monitoring system (in working chamber)
- Fully stainless-steel external chassis
- SCADA Control system CFR 21 part 11 compliant
- Glove leak tester (Safeglove)