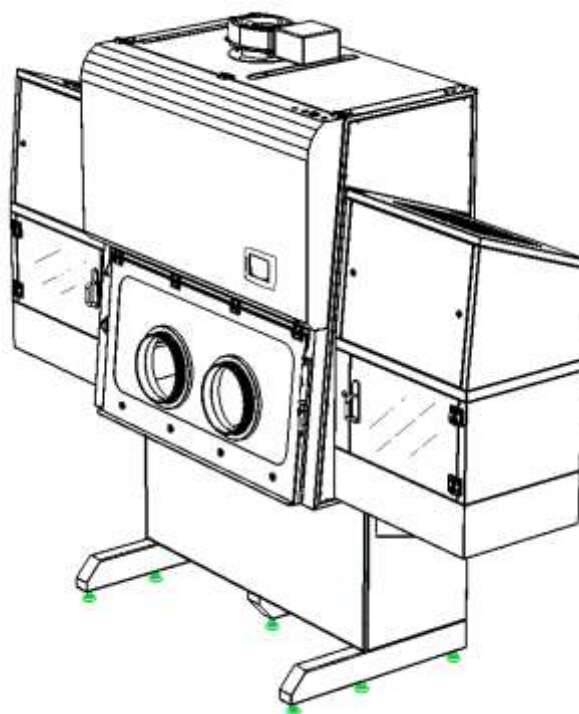


BIOAIR

ISOLATION TECHNOLOGY

ISOMATE



Summary

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1 DESCRIPTION

ISOMATE Steri is a positive pressure isolator, designed to ensure product and process protection during all activities requiring a sterile environment, and avoiding the risk of external contaminants pollution.

Product protection is achieved via the creation of a positive pressure inside the working area with respect to the surrounding environment.

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.

Two centrifugal motorblowers maintain the correct airflows and pressure gradients.

All internal surfaces are built in AISI316 stainless-steel.

2 GUIDE LINES & REFERENCE NORMATIVES

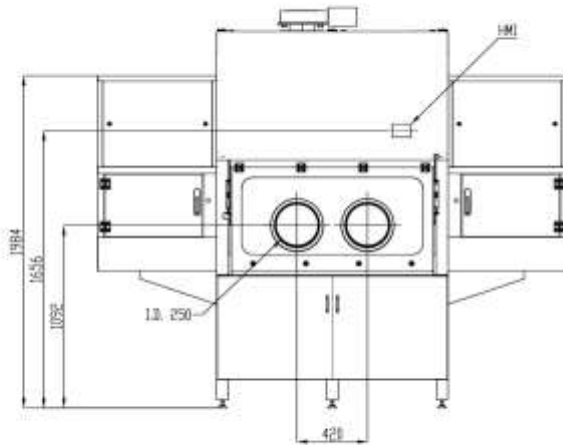
Rif	Standard	Description
[A]	ISO 14644-1	Cleanrooms and associated controlled environments
[B]	ISO 14644-7	Separative devices
[C]	EU GMP	EudraLex Good manufacturing practice
[D]	EN 1822-1	High Efficiency Air Filters
[E]	CEI EN 61010-1	Safety requirements for electrical equipment for measurement, control 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

3 MAIN SPECIFICATIONS

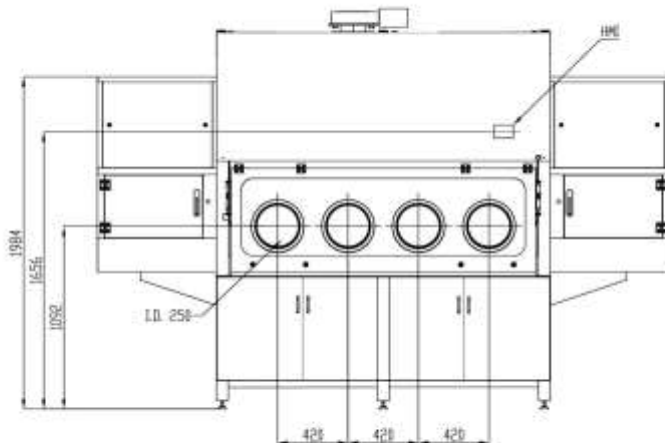
- Inlet air filter: HEPA H14 efficienza 99,995 MPPS (particelle 0,12 – 0,24 μm), \geq 99,999 DOP (0,3 μm).
- Main chamber downflow filter: HEPA H14 efficienza 99,995 MPPS (particelle 0,12 – 0,24 μm), \geq 99,999 DOP (0,3 μm).
- Exhaust air filters on each passbox: HEPA H14 efficienza 99,995 MPPS (particelle 0,12 – 0,24 μm), \geq 99,999 DOP (0,3 μm)
- Inner chamber cleanliness classification: ISO 3 according to ISO 14644-1
- Leaktightness 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.
- Dual wall design. The positive pressure volumes are surrounded (on the side and on the back) by negative pressure area to ensure safety.
- 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 color 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 2 GLOVES



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)