



SHIELDED GLOVE BOX

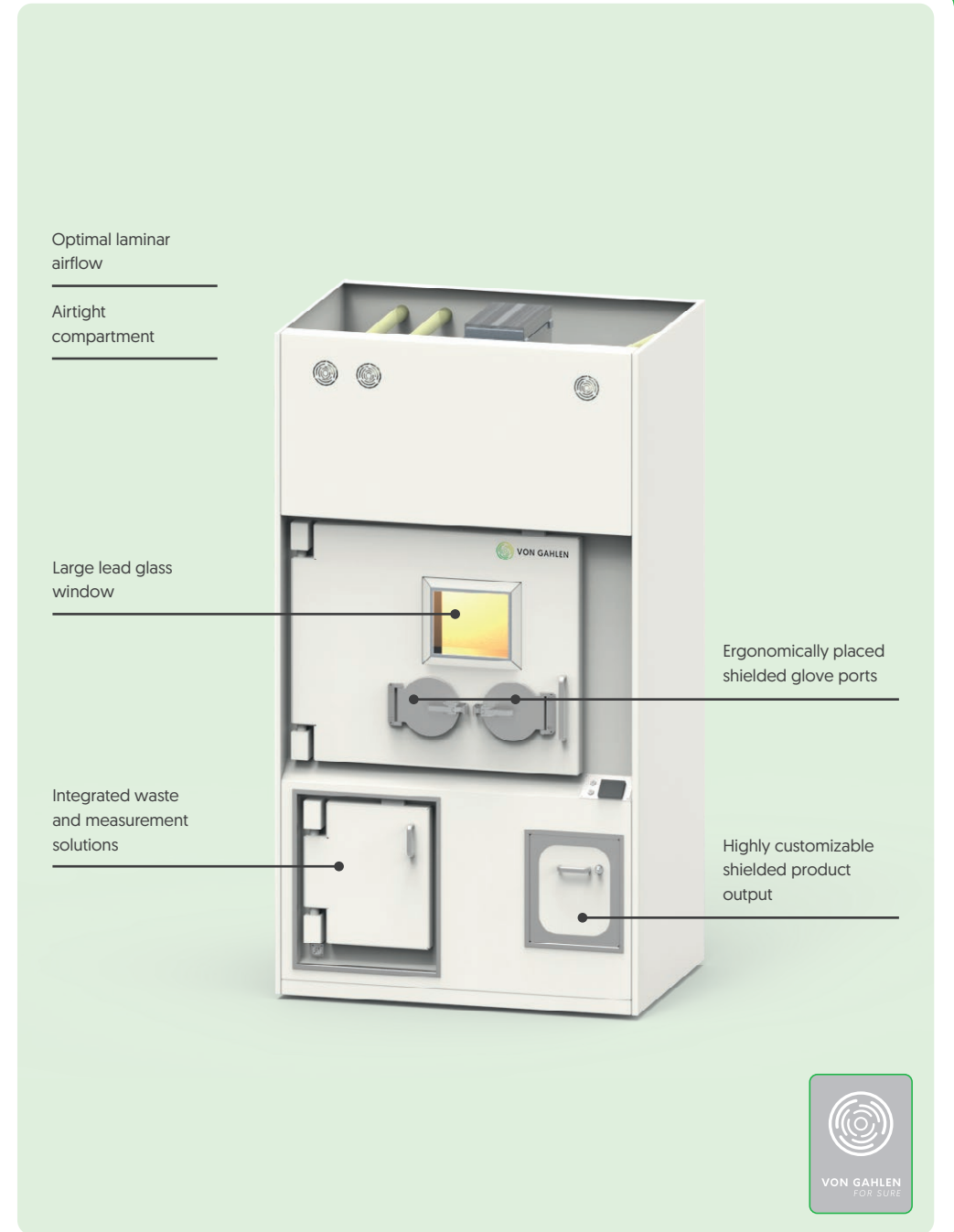
The shielded glove box model is designed for aseptic handling of sterile radiopharmaceutical solutions. The integrated laminar downflow system ensures a sterile environment that complies with the current Good Manufacturing Practices (GMP) class A standards.

This complete solution can be continuously integrated into a clean room. This hot cell contains a shielded compartment with 50 mm lead shielding in all directions and an airtight stainless-steel box with rounded corners. The Glove box offers flexibility by adding an airlock or a preparation glovebox. These compartments help to establish the required cascade design according to GMP requirements.

Trust in our shielded glove box to ensure the highest pharmaceutical production standards while safeguarding both operator and manipulated products.

The hot cell is available in two sizes.

Variants	SGB	SGB-XL
Outside dimensions (mm) [W*D*H]	1.115*1.421*2.650	1.470*1.421*2.650
Inside dimensions (mm) [W*D*H]	709*719*790	1.024*719*790
Weight @50 mm shielding (Kg)	7.260	8.325
Lead glass(mm) [W*H]	250*250	300*250
Effective door opening mm [W*H]	620*685	620*685
Exhaust (m3 / hr)	62	90



The images shown are for illustrative purposes only. The actual product may vary in design, color, and specifications.

STANDARD FEATURES

Radiation protection

- 50 mm lead shielding in all walls, roof and floor.
- Lead glass window in front door (lead wall equivalent).
- Shielded ion chamber (lead wall equivalent) suitable for our commonly used Dose calibrators.
- Solid waste vault shielding (50 mm lead shielding).

Sample & product handling

- Internal stainless steel 316L box with special micro-surface treatment.
- (Shielded) pass through to adjacent compartment 200*250 mm (W*H).
- Ionization chamber lift system with foot pedal control.
- Glove ports in front door for ergonomic manual handling in the cell.
- Acrylic inner door (hinged left) with inflatable seals to maintain airtight integrity.
- Product Retrieval Drawer, including Von Gahlen Type-A transport container (on the front side).

Air handling / distribution

- Integrated laminar down flow over entire working surface [99,995% efficient HEPA H14 filter]. *
- Homogeneous air velocity of 0.36-0.54 m/s.
- Leak tightness according to ISO10648-2 Class 3 (<1% hourly leak rate).
- Air inlet: with HEPA filter (H13), including valve.
- Air exhaust: including valve.



Cleaning

- ISO14644-1/ GMP annex 1 compliant interior surface finish for cleaning, validation and decontamination.
- Exterior finish traffic white (RAL 9016), easy to clean.
- Prepared for validated and compliant surface bio-decontamination with 35% Hydrogen Peroxide Vapor technology utilizing Registered Hydrogen Peroxide Sterilant (EPA Registration Number: 72372-1-86703).

System operation / control

- Control via human-machine interface (HMI) with touch screen.
- Stable temperature (max. variation to clean room temperature: + 5 °C).
- Light intensity min 500 Lux.
- Visible and audible alarms.

Sensors

- Digital pressure measurement on all compartments.
- Standard particle counter, incl. isokinetic probe.
- Measuring the pressure drop over the downflow filter.
- Temperature and humidity sensors.

Utilities

- Electrical outlets inside the hot cell, switchable from HMI [in accordance with local requirements].
- Airtight pass-through for custom entry of tubes and cables.
- Dose calibrator.

OPTIONAL FEATURES

- Several GMP Class A and/or B pre-chambers ** (required to transfer materials to the Class A compartment).
- Customizable product retrieval drawer to the rear or side.
- Radiation detection system including safety interlock.
- Acid-resistant box material (Hastelloy / Kydex) upon request.
- End-to-end contamination control and cycle development ,including Hydrogen peroxide vapor decontamination generator.
- Autoclave integration (autoclave including validation).
- Glove tester.
- Monitor and / or laptop mount.

Dispensers / filling systems.

- Open vial dose divider semi-automatic [OVDD-CAN].
- Closed vial dose divider semi-automatic [CVDD-CAN].
- Closed vials and syringe dose dispenser [ADD].

