

TIMOTEC



ISOLATORS

**Customized
Solutions**

Together we create individual solutions

Our main specialization is the production of customized isolator technology – precisely tailored to the specific requirements of our customers. We also offer standardized product lines that represent well-proven solutions for common applications.

STANDARDS AND CERTIFICATIONS

Our production processes and products comply with international standards ISO 14937, GMP guidelines (EudraLex Volume 4), standards ČSN EN ISO 14644-7 and other regulations, ensuring the highest quality and safety.



- INDIVIDUAL CUSTOMER CARE THANKS TO OUR OWN DESIGN AND DEVELOPMENT DEPARTMENT
- FLEXIBLE IMPLEMENTATION OF SPECIFIC CUSTOMER REQUIREMENTS
- WELL-THOUGHT-OUT DESIGNS AND FUNCTIONAL SOLUTIONS
- PRECISE MANUFACTURING TO THE HIGHEST QUALITY STANDARDS
- USE OF ROBUST AISI 304 AND AISI 316L STAINLESS STEEL, 3mm
- HIGH RESISTANCE TO DEMANDING CONDITIONS OF USE (cleaning agents, decontamination)
- POSSIBLE INTEGRATION OF EXTERNAL DEVICES

LAMINAR
ISOLATORS



Laminar isolators are designed to create a clean and sterile environment and to protect the product being processed or the operator.

CLEANLINESS CLASS „A“

TIGHTNESS CLASS 3

According to ISO 10648-2.

LAMINAR FLOW, 0,45 m/s ±20%
(864-1533 h⁻¹) depending on the chamber volume.

CONSTRUCTION MATERIAL

Shell material - AISI 304 stainless steel. Chamber - AISI 316L stainless steel and plastics (certified, FDA CFR 21).

OPERATION IN MODE

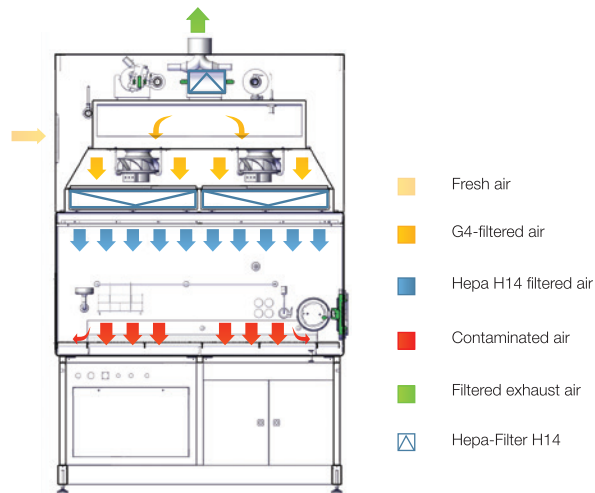
Overpressure or underpressure.

H₂O₂ DECONTAMINATION OPTION

Separate chambers with separate ventilation systems.

APPLICATION

- Filling sterile injection solutions and infusions.
- Aseptic preparation of drugs in hospital departments.
- Working with cell cultures and viral vectors.
- Preparation of sterile media in biotechnology.
- Microbiological tests under aseptic conditions.
- Advanced gene therapies
- Sterility tests.



TURBULENT
ISOLATOR



Suitable for manufacturers of active pharmaceutical ingredients (API category OEB-6) and oral solid dosage forms (OSD). Ensures safety for both the production team and the product.

CLEANLINESS CLASS „C“

TIGHTNESS CLASS 3

According to ISO 10648-2.

TURBULENT FLOW
(5-40 exchanges/hour).

CONSTRUCTION MATERIAL

Shell material - AISI 304 stainless steel. Chamber - AISI 316L stainless steel.

OPERATION IN MODE

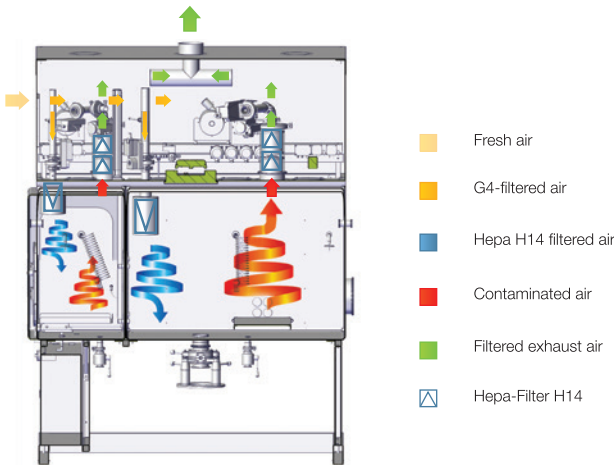
Overpressure or underpressure.

H₂O₂ DECONTAMINATION OPTION

Separate chambers with separate ventilation systems.

APPLICATION

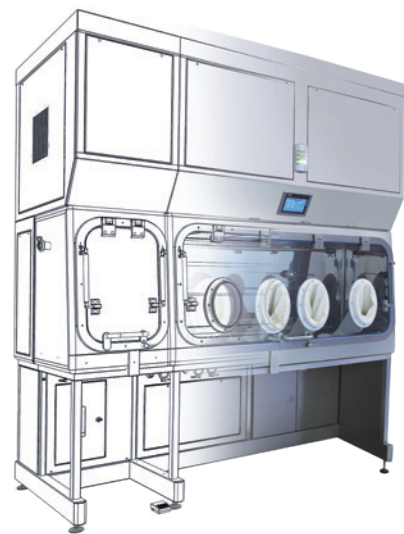
- Manufacturing of cytotoxic drugs.
- Handling HAPI and API, toxic powders, and chemicals up to OEB-6.
- Weighing and mixing hazardous ingredients.
- Industrial applications involving hazardous aerosols or gases.





- MANUFACTURED IN ACCORDANCE WITH GMP STANDARDS
- LAMINAR/TURBULENT
- OPERATION IN OVERPRESSURE OR UNDERPRESSURE MODE
- AUTOMATIC LEAK TEST
- HEPA FILTRATION H14
- CHECKING FILTER CONTAMINATION
- MOCK-UP, FAT, SAT, IQ/OQ
- INFLATABLE SEAL (SILICONE)
- OPTION OF VALIDATED DECONTAMINATION USING HYDROGEN PEROXIDE H₂O₂ (SAL 10⁻⁶)

STANDARD
CHAMBER DIMENSIONS



Labeling	Number of cuffs	Width (mm)	Height (mm)	Depth (mm)
PK1800	4	1800	900	650
PK1500	3	1500	900	650
PK1350	3	1350	900	650
PK1000	2	1000	900	650
PK600	0 or 1	600	900	650

Surface treatments (chambers and HS, frames always sanded)				
Standard	Vibrated	Ra≤0,6µm	Vibrated	Ra≤0,8µm
Option	Vibrated	Ra≤0,6µm	Glossy	Ra≤0,1µm
Option	Glossy	Ra≤0,6µm	Glossy	Ra≤0,1µm

CHAMBER

- FULLY WELDED WORKING CHAMBER
- EASY-TO-CLEAN DESIGN
- SLOPED BOTTOM WITH VALVE
- SAFETY GLASS
- TILTING FRONT GLASS
- SAFE GLOVE CHANGE
- CABLE GANGUAGES

CONTROL SYSTEM

- HMI PANEL
- SENSORS (TEMPERATURE, AIR)
- VISUAL AND AUDIBLE ALARM
- PRESSURE SAFETY VALVE
- MAIN SWITCH

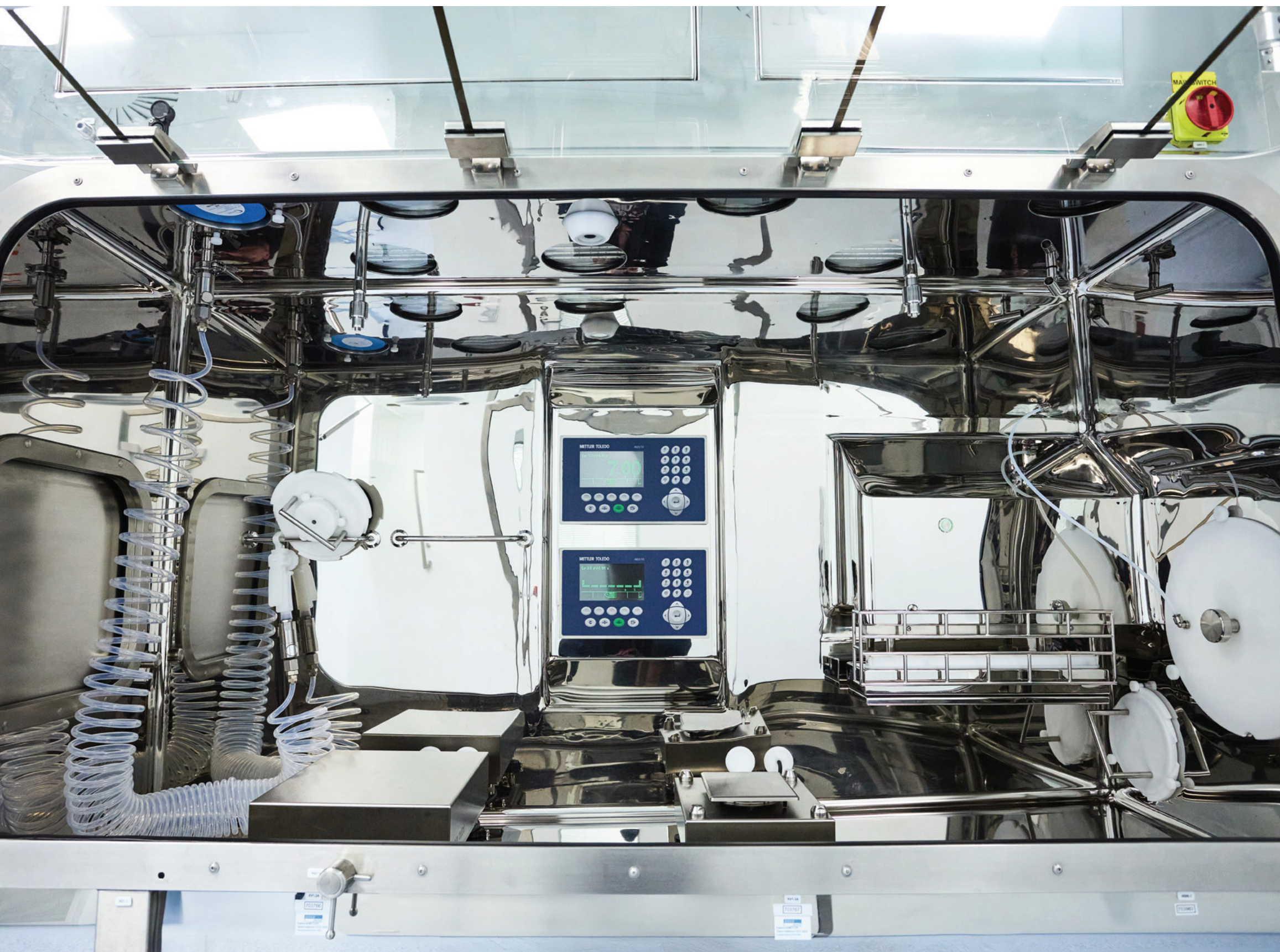
EQUIPMENT

- INFLATABLE SEAL
- BUILT-IN LED LIGHTS
- HANGING SHELF SYSTEM
- LAMINAR FRAME
- PERFORATED GRATES
- DISTRIBUTION PIPING FOR H2O2
- MATERIAL PASS-THROUGH
- TRI-CLAMP VALIDATION PORT
- SOCKETS for powering additional equipment
- FOOT SWITCH
- SLIDING DOOR
- SHOWER
- H14 HEPA FILTERS
- SINGLE GLOVES

STANDARD
EQUIPMENT



„ Together we
create individual
solutions



OPTIONAL EQUIPMENT

ATEX modification

SOFTWARE gemäß 21 CFR Part 11 (Audit Trail)

SOFTWARE according to 21 CFR part 11 (audit trail).

DECONTAMINATION – Catalytic plates, Catalyst, UVC light, H₂O₂ distribution (integrated PURITER), Preparation for H₂O₂ (external systems).

MONITORING – Microbial monitoring, Particle monitoring.

ROUND SLEEVE FLANGES D300 mm SLEEVES

GLOVES – two-piece (safe change), standard design.

CONTROL AND DATA COLLECTION – SCADA, WinCC, UPS.

EQUIPMENT– Centrifuge, Microscope, Camera, Stirrer (magnetic), Sterility test pump, Automatic CIP shower, Freeze dryer, Paddle dryer (3V tech) 1199, Touch screen, Display screen, WIP shower, Welder, Titrator, Scales + terminal, Glass reactor.

TRANSFER – Centrifuge, Microscope, Camera, Stirrer (magnetic), Sterility test pump, Automatic CIP shower, Freeze dryer, Paddle dryer (3V tech) 1199, Touch screen, Display screen, WIP shower, Welder, Titrator, Scales + terminal, Glass reactor.

VALIDATION – DQ, IQ/OQ, Smepak.

INCUBATOR

SENSORS – CO₂ sensor in the chamber, H₂O₂ HC sensor (high concentration in the chamber), H₂O₂ LC sensor (low concentration in the chamber), O₂ sensor in the chamber.

ACCESSORIES – Wire program, Glove holders, Stainless steel glass springs, Chamber sockets (230V, USB, Ethernet, etc.), Lighting for sensitive materials (red, orange, etc.).

REFERENCES



TIMOTEC



www.timotec.eu

TIMOTEC processes with TÜV SÜD Certification:

ISO 9001:2016

ISO 14001:2016

ISO 45001:2018 (OHS)