

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 $\pm$ 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

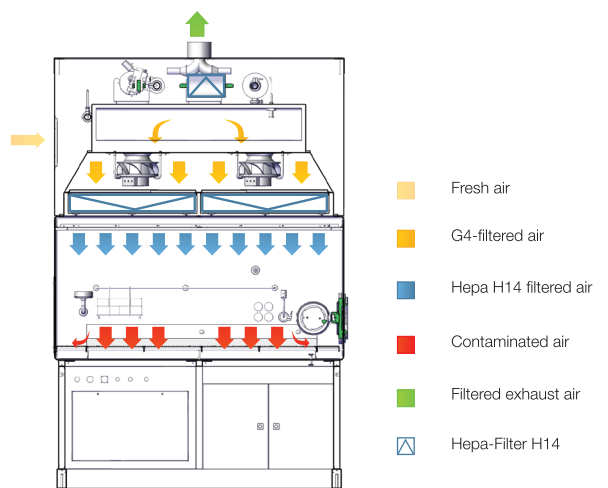
Overpressure or underpressure.

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

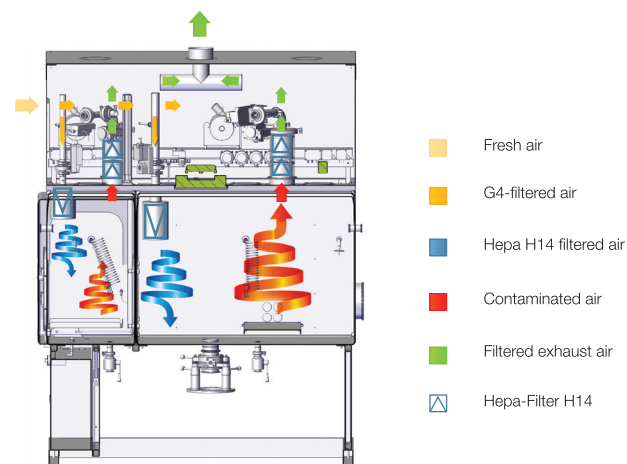
Overpressure or underpressure.

H₂O₂ DECONTAMINATION OPTION

Separate chambers with separate ventilation systems.

APPLICATION

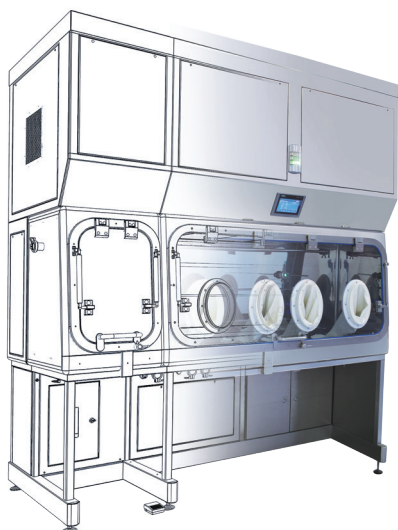
- Manufacturing of cytotoxic drugs.
- Handling HAPI and API, toxic powders, and chemicals up to OEB-6.
- Weighing and mixing hazardous ingredients.
- Industrial applications involving hazardous aerosols or gases.





- 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 H_2O_2 (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	$Ra \leq 0,6\mu m$	Vibrated	$Ra \leq 0,8\mu m$
Option	Vibrated	$Ra \leq 0,6\mu m$	Glossy	$Ra \leq 0,1\mu m$
Option	Glossy	$Ra \leq 0,6\mu m$	Glossy	$Ra \leq 0,1\mu m$

STANDARD EQUIPMENT

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



„ 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, H_2O_2 distribution (integrated PURITER), Preparation for H_2O_2 (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 – CO_2 sensor in the chamber, H_2O_2 HC sensor (high concentration in the chamber), H_2O_2 LC sensor (low concentration in the chamber), O_2 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)