

ASEPTIC ISOLATOR

When it comes to aseptic, CPS is the expert. We know from beginning to end what it takes to design, build, test, install, operate, and validate an aseptic environment and have done so all over the globe. Our aseptic isolators are custom tailored to your unique application needs.



ICS helps you to successfully address barrier technology challenges from the initial development stages to the final handling of the product. Our aseptic products are meticulously designed and crafted to maintain an ISO 5/Grade A sterile production space.

APPRECIATE THE ART OF ENGINEERING

ASEPTIC ISOLATOR SPECIFICATIONS

ICS ASEPTIC ISOLATORS ARE DESIGNED FOR COMPLIANCE WITH YOUR LOCAL REGULATORY BODY SUCH AS:

- ISO 14644-1 Cleanroom & Associated Controlled Environment
- EU/EMA - European Union/The European Medicines Agency
- FDA and EU cGMP's (current Good Manufacturing Practices)
- ISPE guidelines (The Society of Pharmaceutical and Medical Device Professionals)
- FDA (Food and Drug Administration)
- MCA (Medical Control Agency)
- AGS - American Glovebox Society Guidelines
- FS 209E Airborne Particulate Cleanliness
- WHO - World Health Organization
- ICH - International Conference on Harmonization
- SFDA or many others
- CFDA - China Food and Drug Administration
- and many others...

STANDARD OPTIONS

- Fully Integrated and Automated VHP Bio decontamination - 6 Log Reduction
- PLC Control
- 6" Color touchscreen control interface - diagnostics and configurable recipes
- UL 508A Listed Electrical Panels
- Explosion-Proof / ATEX
- Rapid Transfer Ports (RTP)
- Airlocks
- Integrated Viable and Non-Viable Particulate Monitoring
- Yellow LED lighting for light sensitive products
- Uninterruptable Power Supply (UPS)
- Laminated safety glass windows
- Control interlocked doors
- FDA 21CFR Part 11 - Electronic Signatures and Record Control System
- Glove tester

STANDARD FEATURES

- Cove corner interior design
- Gull-wing lift up doors
- Oval glove ports
- Tempered glass windows
- Positive or Negative pressure operation based on application
- ULPA Filtration
- Un-directional airflow

APPLICATIONS

- Sterile Fill Finish Lines
- Sterile Filtering
- Ampule Filling
- Syringe Filling
- Sampling
- Sample Testing
- Sterility Testing

