



**Iskra pio** d.o.o.  
Industrial equipment manufacturer

MAXIMUM PROTECTION

ISOLATORS



Operator, product and environment protection  
ISO 5 (ISO 14644-1:1999), Class A (GMP)  
OEB5 (<1µg/m<sup>3</sup>)  
ATEX (Ex II 2GD)



Isolators ensure the highest level of protection for the operator, product and environment and are suitable for handling the most dangerous substances or protecting the most sensitive processes. We offer complete solutions (from concept to manufacturing) for containment, aseptic and aseptic-toxic isolators.

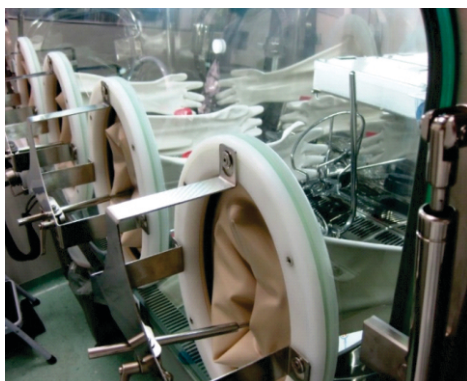


**Applications**

- sampling
- weighing
- dispensing
- repackaging
- sieving/milling
- granulation line
- synthesys
- analytics
- sterility testing
- encapsulation
- research and development
- in process control
- washing

**Main features**

- ISO 5 (ISO 14644-1:1999) all cleanliness classes
- class A (GMP)
- safety levels up to OEB 5 (<1µg/m<sup>3</sup>) - validated by OEL test
- controlled positive/negative pressure
- HEPA filtration of inlet and circulating/exhaust air
- sterile/safe material transfer
- safe filter change
- safe glove change
- efficient cleaning
- inert/normal atmosphere
- turbulent/laminar air flow
- easy and efficient control
- GMP construction
- made of AISI 316L
- rounded corners, ergonomic design
- FDA conforming materials
- integrated equipment



In cooperation with a customer we develop an isolator regarding the process requirements (sampling, weighing, dispensing, sterility testing...). Dimension, shape, number of gloves, additional equipment, and atmosphere are adjusted to planned work and are finally determined on a real size steel MOCK UP model. With our experience we can offer the most suitable equipment solution for our costumers' needs.



### Possible options:

- VHP sterilization system
- ATEX execution (Ex II 2GD)
- particle monitoring
- microbiological air sampler
- specific atmosphere controls (temperature, humidity, oxygen level), inert atmosphere
- spray gun, liofilizators, drying ovens, mixers, mills, equinox pump, A/B port, weighing scales...
- equipment for supervision and control of weighing process
- welding tongs - device for sealing bags
- glove testers
- shelf holders
- safe waste removal - continuous liner system (CLS) or DTPE port
- lifting system
- drum clamping and tilting mechanism
- needle for purging with nitrogen or with other gasses
- platform for operator
- pass through benches
- zip-bag system
- round or oval glove ports
- different gloves - resistant, sizes, types, safe changes
- CFR part 11, GAMP 5 conform system
- Custom made for specific purposes



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