Key Features and benefits

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- Single pass turbulent flow (EU GMP grade A) to maintain sterile conditions inside the isolator.
- The glass vision panels are ‘gull wing’ type which hinge upwards and outwards. In the open position the doors are held open with gas struts.
- Inflatable seal technology on all doors assures very low leakage rate in compliance with the most stringent leakage criteria stated in ISO 14644-7.
- High resistance to H2O2 without giving rise to excessive out gassing and thus minimising bio-decontamination cycle time.
- Design suitable for bio-decontamination using a broad range of systems to fulfill user requirements:
  - Integrated VHP (vaporized hydrogen peroxide) generator
  - Stand-alone VHP (vaporized hydrogen peroxide) generator
  - Unique Telstar Integrated iHP™ system (ionized Hydrogen Peroxide) generator offering the most effective bio-decontamination solution.
  - PLC-based user-friendly automated control with automatic leak-test function (pressure hold test).
- As standard the units includes:
  - Internal Temperature monitoring sensor.
  - Internal Humidity monitoring sensor.
  - Telstar Ø200mm ‘CTS’ transfer port is offered in the end wall for the removal of waste materials.
- Oval shaped gloveports which are designed for sound ergonomic posture while maximising operator arm movement.
- Gloves are a Three-part design which enables changing of a glove without compromising isolator sterility.
- Grade AISI 316L stainless steel, fully welded, crevice free with smooth internal surfaces guarantees complete cleanability.
- Support frame manufactured from AISI 304L stainless steel.
- Lighting fixtures within each chamber with external access for maintenance.
Five types of Sterility Test Isolators are available in the Telstar standard range. Isolators type 1, 2 & 3 are for small scale sterility testing and choice of model is dependent on the number of tests to be performed. These Isolators are designed for single loading sterility testing; the Isolators are pre-loaded with samples and test materials before bio-decontamination. After bio-decontamination the tests are carried out and then the Isolator is closed down at the end of the testing.

Type 1 – Single Chamber Isolator with 2 gloves, recommended for up to 2 test samples per batch/day

Type 2 – Single Chamber Isolator with 3 gloves, recommended for up to 6 test samples per batch/day

Type 3 – Single Chamber Isolator with 4 gloves, recommended for up to 10 test samples per batch/day

Type 4 – Double Chamber Isolator (main chamber with 4 gloves + transfer chamber), recommended for over 10 test samples per batch/day. (Approximately 20 tests could be carried out in an 8hr period)

Type 5 – Double Chamber Isolator (main chamber with 3 gloves + transfer chamber), recommended for over 10 test samples per batch where space restriction are applicable on site. (Approximately 20 tests could be carried out in an 8hr period)

A comprehensive range protecting the most critical step in production process...

Sterility testing of sterile pharmaceutical products is required by the Pharmacopoeias to determine acceptability of a production lot. It is an essential element of sterilization validation and it must be performed in a manner which avoids the risks of both false positive and false negative results.

False positive results are generally due to laboratory contamination from the testing environment or technician/technique error and cause additional work in terms of extra documentation required and adds significantly to cost as it delays or prevents release of the product for sale.

The Telstar range of rigid wall Sterility Test Isolators are designed to avoid this risk and protect the product from both the process and externally generated factors that would compromise its quality.

The Telstar ACE Sterility Test Isolator has been developed to cover a wide variety of clients’ needs. The units’ ability to provide a reliable aseptic environment for sterility testing and other aseptic processes is unquestioned. A minimum of log 6 reduction in spore forming micro-organisms is consistently achieved & validated using a BI challenge.

Sound ergonomic design of the unit is combined with thoughtful design for manufacture utilising the latest techniques, assuring ease of assembly and efficient inspection and testing.

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The Isolator complies fully with ISO 14644-7:2004 producing an EU GMP Grade A environment throughout the chamber.

The Telstar range of Sterility Test Isolators is suitable for performing both Direct Inoculation and Filter Membrane sterility tests with flexibility to be bio-decontaminated by different types of bio-decontamination systems available.

Additionally there is a choice of optional equipment which can be selected by the client to meet specific requirements.

Factory Fitted Options

- Bio-decontamination System
- Sterility Test Pump
- Glove Tester
- Paperless Chart Recorder
- Automated raise/lower Support Frame
- H2O2 external Monitoring Sensor
- Alternative types of Transfer Ports
- Internal Shelving & Racking

Ancillary Options

- Non Viable Monitoring
- Viable Monitoring
- Continuous liner Grommet for Gamma Irradiated liners or bags.
- Continuous Liner bag welder
- Bag Welder mobile trolley

Telstar Range of sterility test Isolators

Isolators type 4 & 5 are used for continuous batch testing where large numbers of sterility tests need to be performed. The Isolator is pre-loaded with the initial samples and test materials before bio-decontamination, after bio-decontamination the sterility testing can proceed. Additional functionality with these Isolator models is that additional test materials and samples can be introduced and bio-decontaminated via the Transfer Chamber while sterility testing is taking place in the main chamber. The sterility testing process can then be continuous; transferring samples and test materials into the isolator without detriment to the working environment.
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Telstar Range of sterility test Isolators

Telstar Integrated iHTM system

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Sterility Test Isolator