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CASE STUDY FILE: STERILITY TESTING

ISOSPHEREST

STERILITY TESTING ISOLATORS
WITH H₂O₂ DECONTAMINATION

CUSTOMER: FDA

APPLICATION:

cGMP sterility testing

FEATURES:

- C8 model 8' with 4 gloves for sterility testing.
- C4 model 4' with 2 gloves for sterility testing
- Iso5 unidirectional airflow.
- Lift system
- 316 stainless steel with tempered glass.
- Inflatable seal.
- H₂O₂ decontamination and integration.
- Millipore sterility pump integration
- Alpha Beta doors
- Allen Bradley HMI/PLC

SPECIFICATIONS:

- H₂O₂ integration & faster decontamination cycle for both the C8 and C4
- Fast recovery rate.
- 1 PLC & HMI to control both the isolator and the H₂O₂ generator.
- H₂O₂ generator can decontaminate both the C8 and C4 units
- Turnkey solution: equipment integration, interfacing, start-up, training, validation (IQ/OQ/PQ) for full cGMP compliance.
- C4 is mobile for materials transfer.



**Vertical unidirectional laminar airflow
(60 Feet/Min.@12 inches)**

**ALL TRANSFER CHAMBER DOORS MADE OF TEMPERED
GLASS WITH AN INFLATABLE GASKET.**

