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CASE STUDY FILE: ASEPTIC FILLING

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SMALL VOLUME ASEPTIC FILLING
ISOLATOR SYSTEM

CUSTOMER: INTASPHARMA / PHARMIDEA

APPLICATION:

cGMP Hazardous & non-hazardous, small volume aseptic filling and manufacturing

FEATURES:

- Multiple glove isolator with small volume aseptic filling equipment
- C4 model 4' with 2 gloves and 1 antechamber transfer.
- Iso5 unidirectional airflow.
- 316 stainless steel with tempered glass.
- Inflatable seal.
- H2O2 decontamination and integration.
- Alpha Beta doors.
- BIBO bag in bag exhaust filtration for hazardous filling
- 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.
- Safe for hazardous filling with fully exhausted system in a BIBO filtration



The overall construction takes a modular approach, with partially assembled panels and structures, in order to be assembled over the filling line at customer site.

