

ISOCLAVE

CIP/SIP
vibratory bowl

Annex-1
compliant

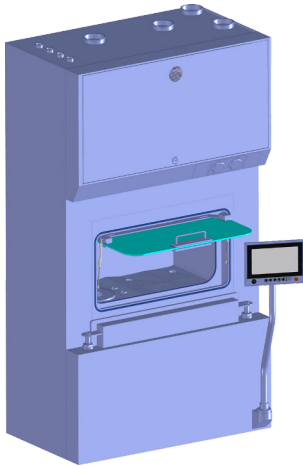
Sanitization
is no longer enough

Ensure True Sterility,
traceable and sustainable

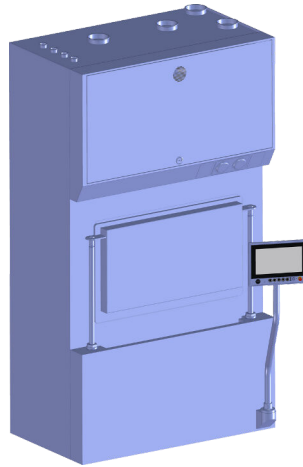
PHIZERO

Isolator - Autoclave - all in one

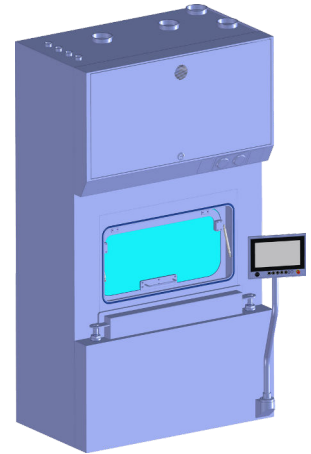
- It's an autoclave (SIP) with integrated:
 - sterile unidirectional flow (grade A)
 - viable/non viable particle monitoring
- It's an isolator sterilized with saturated steam
- It's a washing module (CIP)



set up



steaming



unidirectional airflow

| Description of the steps below in the different equipment types | VHP Sanitized Isolator | Autoclave & Lyo | ISOCLAVE | Evaluation |
|--|--|---|--|--|
| Sterility Assurance level | Log 6 reduction Inhibited by hydrophobic surfaces (e.g. silicon residues) | Log 12 reduction (Overkill approach) Resulting in 10^{-6} SAL | Log 12 reduction (Overkill approach) Resulting in 10^{-6} SAL | Overkill approach, including hydrophobic residues at surfaces |
| Isolator sanitization or sterilization (including larger (in)direct product contact surfaces) | Sanitization. (with e.g. VHP) | Sterilization. (with Steam) | Sterilization. (with Steam) | Most performant sterilization technique selected. (Annex-1 expectation) |
| Product risk (residues) | Risk for oxidation (VHP residues) | No risk (no residues) | No risk (no residues) | No oxidation risk |
| Cycle evaluation | Review cycle report (settings and indirect control points, fragile requalification). | Parametric release (Temperature, Pressure and Time). | Parametric release (Temperature, Pressure and Time). | Reliable, predictable & real time release. (Robust requalification) |
| Filter sanitization or sterilization | Flushed at startup. Surface contact with VHP | SIP through filter. | SIP through filter. | Filter sterilized, no recovery time needed |
| Filter Integrity testing | Aerosol retention. (typically every 6 m) | Water Intrusion test, forward flow, bubble point or equivalent. (every batch) | Water Intrusion test or equivalent. (every batch) | Integrity confirmed before (optional) and after every batch (annex-1). (No recall risk if failure after 6 month) |