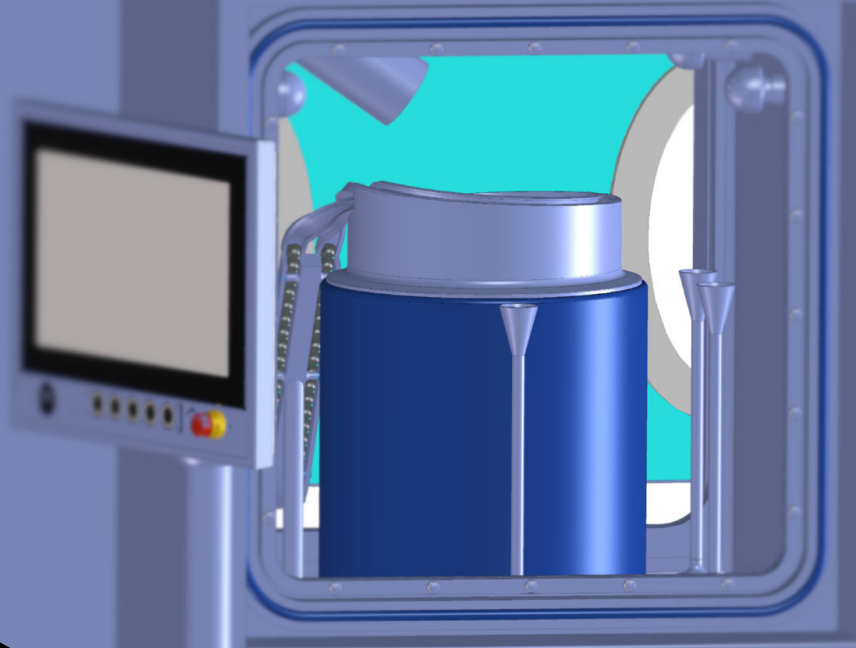


Steri Bowl

for isolators

CIP/SIP
vibratory bowl

Annex-1
compliant



Sanitization
is no longer enough

Ensure True Sterility,
traceable and sustainable

PHIZERO

CIP/SIP of Stopper Bowl



- 1) Protection of membranes that segregate the process and technical chambers to withstand pressure differentials
- 2) Vibratory bowl with integrated SIP/CIP function
- 3) Gloveless unblocking system for vibratory lane and vibratory bowl
- 4) Steamsterilized absolute filter (no HEPA) & diffusor (no CG cloth)
- 5) Steamsterilized path to Viable & Non-viable monitoring

Description of the steps below in the different equipment types	VHP Sanitized Isolator	Autoclave & Lyo	SteriBowl CIP/SIP	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)