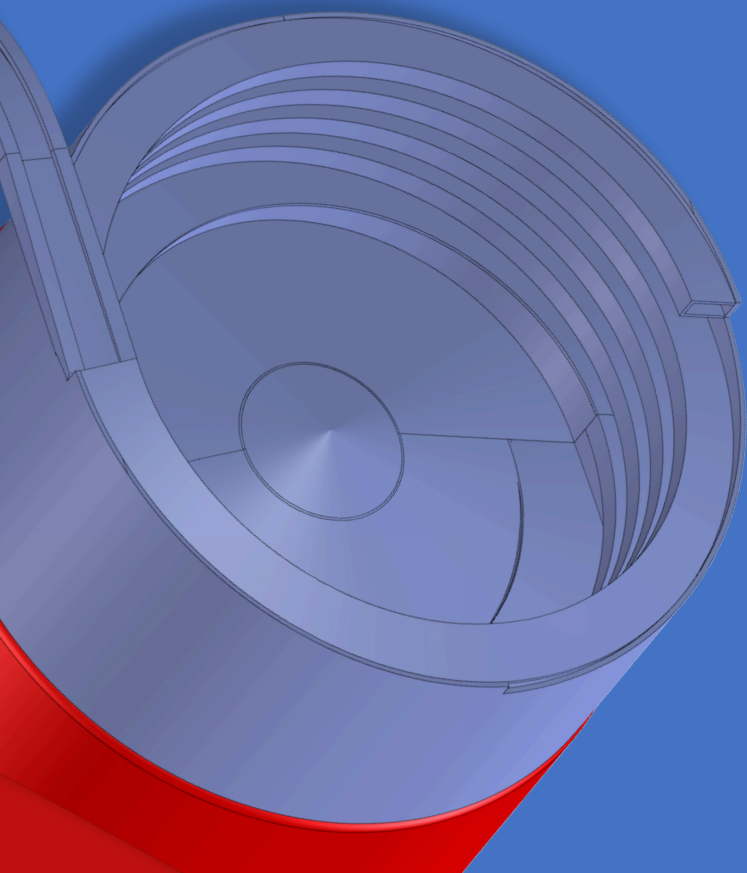
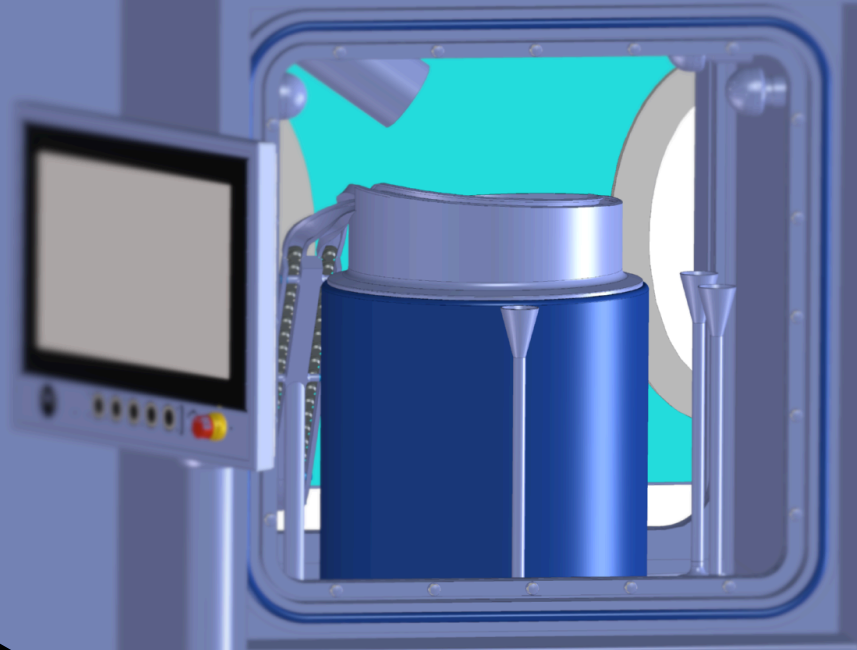


# Steri Bowl

for isolators

CIP/SIP  
vibratory bowl

Annex-1  
compliant



Sanitization  
is no longer enough

Ensure True Sterility,  
traceable and sustainable

**PHI**ZERO

# 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	<b>SteriBowl</b> CIP/SIP	Evaluation
<b>Sterility Assurance level</b>	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
<b>Isolator sanitization or sterilization (including larger (in)direct product contact surfaces)</b>	Sanitization. (with e.g. VHP)	Sterilization. (with Steam)	Sterilization. (with Steam)	Most performant sterilization technique selected. (Annex-1 expectation)
<b>Product risk (residues)</b>	Risk for oxidation (VHP residues)	No risk (no residues)	No risk (no residues)	No oxidation risk
<b>Cycle evaluation</b>	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)
<b>Filter sanitization or sterilization</b>	Flushed at startup. Surface contact with VHP	SIP through filter.	SIP through filter.	Filter sterilized, no recovery time needed
<b>Filter Integrity testing</b>	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)