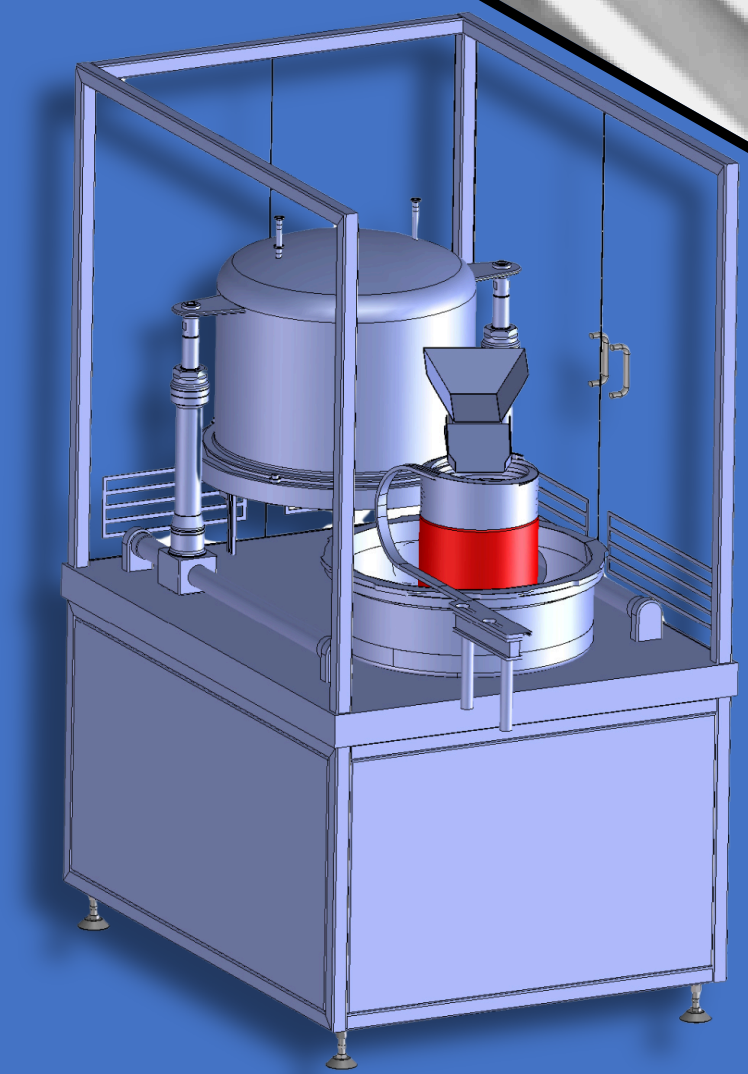
SteriBowl

for RABS

CIP/SIP vibratory bowl

Annex-1 compliant



Sanitization
is no longer enough

Ensure True Sterility,
treaceable and sustainable

PHI ZERO

PHIZERO was born from the union of engineering precision and imagination applied to healthcare. One name, one mission: to help solve the most critical challenges in sterility and reliability.
The industry is living a pivotal moment: the new Annex 1 demands from everyone —manufacturers, integrators, pharmaceutical companies—a higher level of control and to document it in the CCS.
Sanitization is no longer enough and the real challenge, now, is to ensure true sterility, traceable and sustainable.
At PHIZERO we have been working in this direction for years developing a groundbreaking technology that answer the very question we all ask ourselves:
How can I ensure my machines fully comply with Annex 1?
How can I simplify cleaning and sterilization processes without losing productive time?
The answer has a name: SteriBowl™

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)