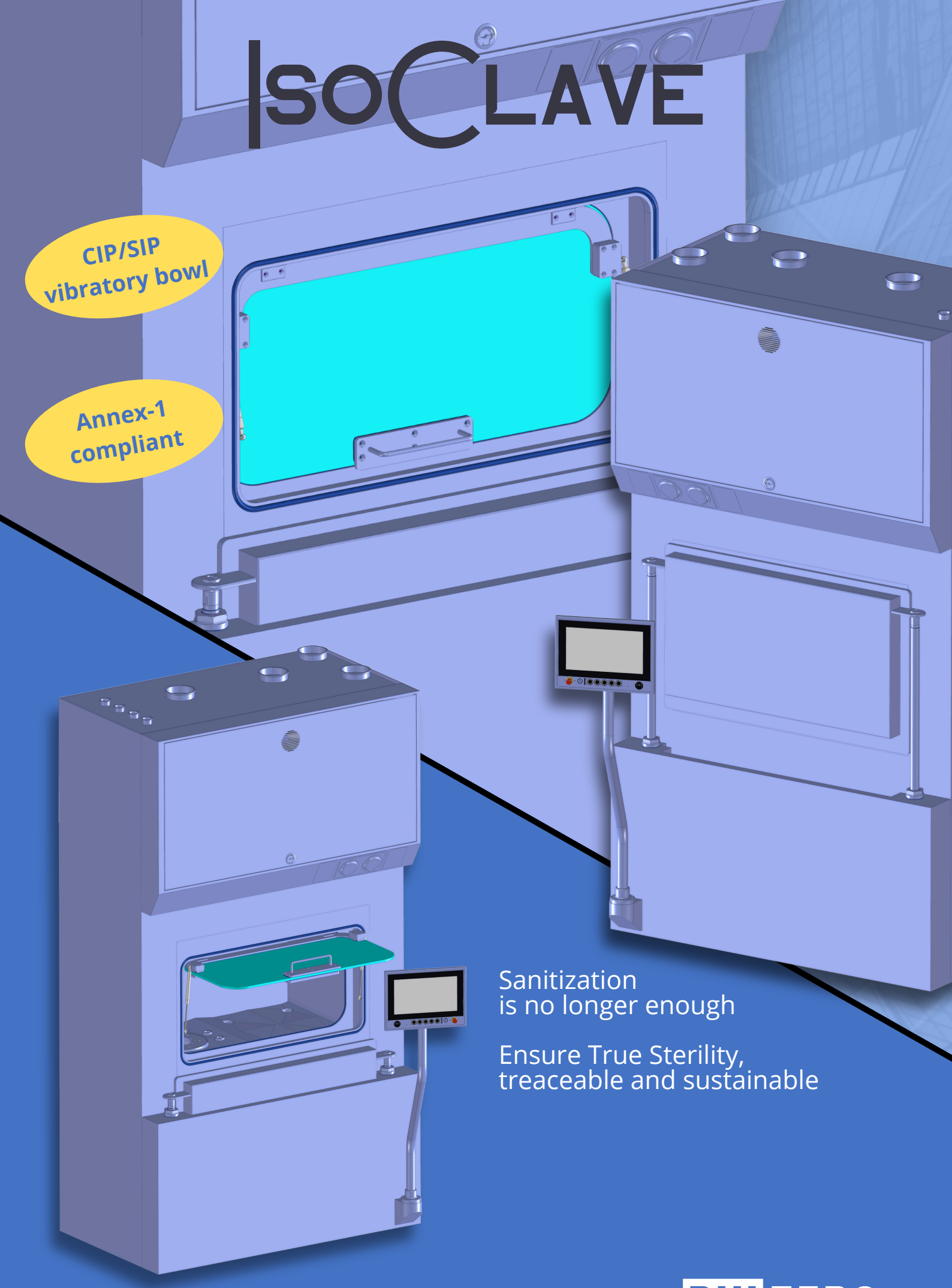
IsoCLAVE

CIP/SIP vibratory bowl

Annex-1 compliant



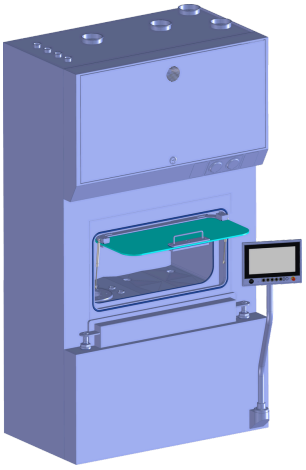
Sanitization
is no longer enough

Ensure True Sterility,
treaceable and sustainable

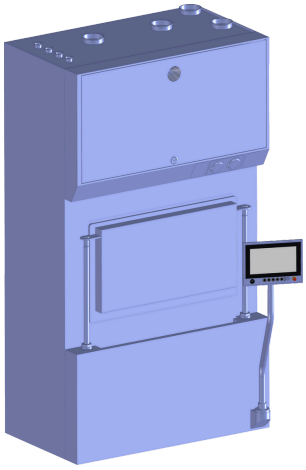
PHI ZERO

Isolator - Autoclave - all in one

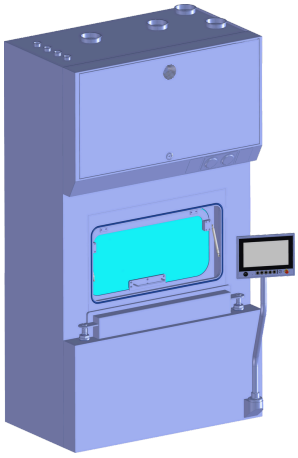
- It's an autoclave (SIP) with integrated:
  - sterile unidirectional flow (grade A)
  - viable/non viableparticle monitoring
- It's an isolator sterilized with saturatedsteam
- It's a washing module (CIP)



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)