

STERYTEMP Plus WHP HIGH SERVICE LIFE FOR HOT AIR FILTRATION

- Intrinsically Hydrophobic PTFE membrane
- High effective enhanced filtering area
- Repeatedly steamable in situ or in autoclave
- Integrity testable
- Bio-Safety per USP-Plastics
- Validation Guide available on request



STERYTEMP Plus filter element is specifically designed for the sterilizing filtration of hot air up to 221 °F (105°C) to feed the reactors in aerobic fermentation processes. The filter media is a hydrophobic expanded PTFE membrane pleated with a specific Polyamid non-woven support resisting to continuous operating high temperature; the design optimises the flow distribution between the filter media and the internal core in order to exploit the full area of the cartridge generating higher throughput and increases service life. STERYTEMP PLUS is manufactured in a controlled environment and each cartridge is integrity tested and is validated for bacterial retention correlated to microbiological challenge test. The retention is checked on regular sampling. PH and PHH grade are supplied with Certification of quality in the box.

MATERIALS OF CONSTRUCTION

Filter media	PTFE expanded membrane
Upstream supports	Polyphenylene Sulfide
Downstream supports	Polyphenylene Sulfide
Internal Core	Polypropylene
External Cage	Polypropylene
End caps/Adapters	Polypropylene

BIO-SAFETY

Filter media and components pass USP Biological Reactivity and Chemical-Physical tests for CLASS VI plastics. The filter meets USP "Water for injection" requirements for particle release and the effluent is Non-Pyrogenic per USP Bacterial Endotoxins (< 0,25 EU/ml). The materials meet FDA CFR 21 requirements

OPERATING CONDITIONS

- max. continuous temperature	221°F (105°C)
- max. cumulative time of steam sterilization	80 hours at 284°F (140°C) with cycles of 60 minutes
- sanitization with chemicals	can be sanitized by standard chemical agents
- max. differential pressure	73 psi at 77°F (5,0 bar at 25 °C)
- recommended change out differential pressure	29 psi at 77°F (2,0 bar at 25 °C)

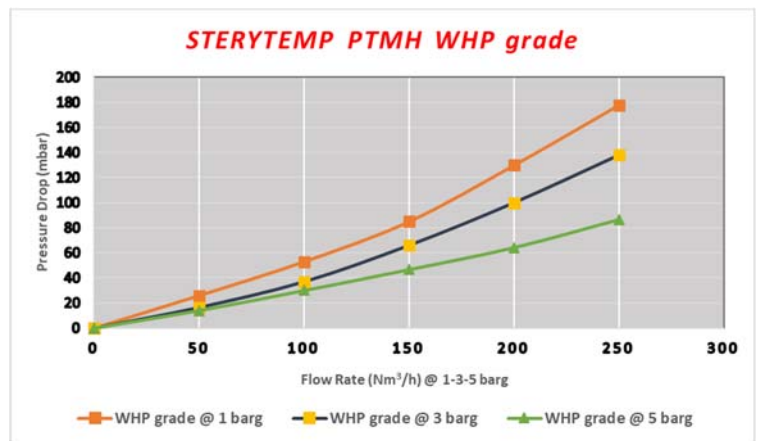
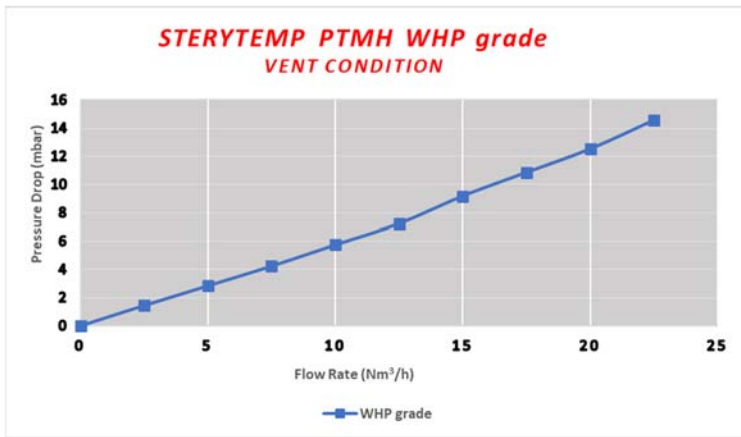
CODE	ABSOLUTE FILTRATION RATING		BACTERIAL RETENTION >10 ⁷ CFU/cm ² (1)	ACCEPTABLE LIMIT FOR DIFFUSION FLOW TEST FOR 10" CARTRIDGE (2)
	IN LIQUID	IN DRY GAS		
WHP	0,2 µm	< 0,01 µm	Brevundimonas diminuta in liquid	≤35 ml/min @ 0.8 barg (11.6 psi)

Note:

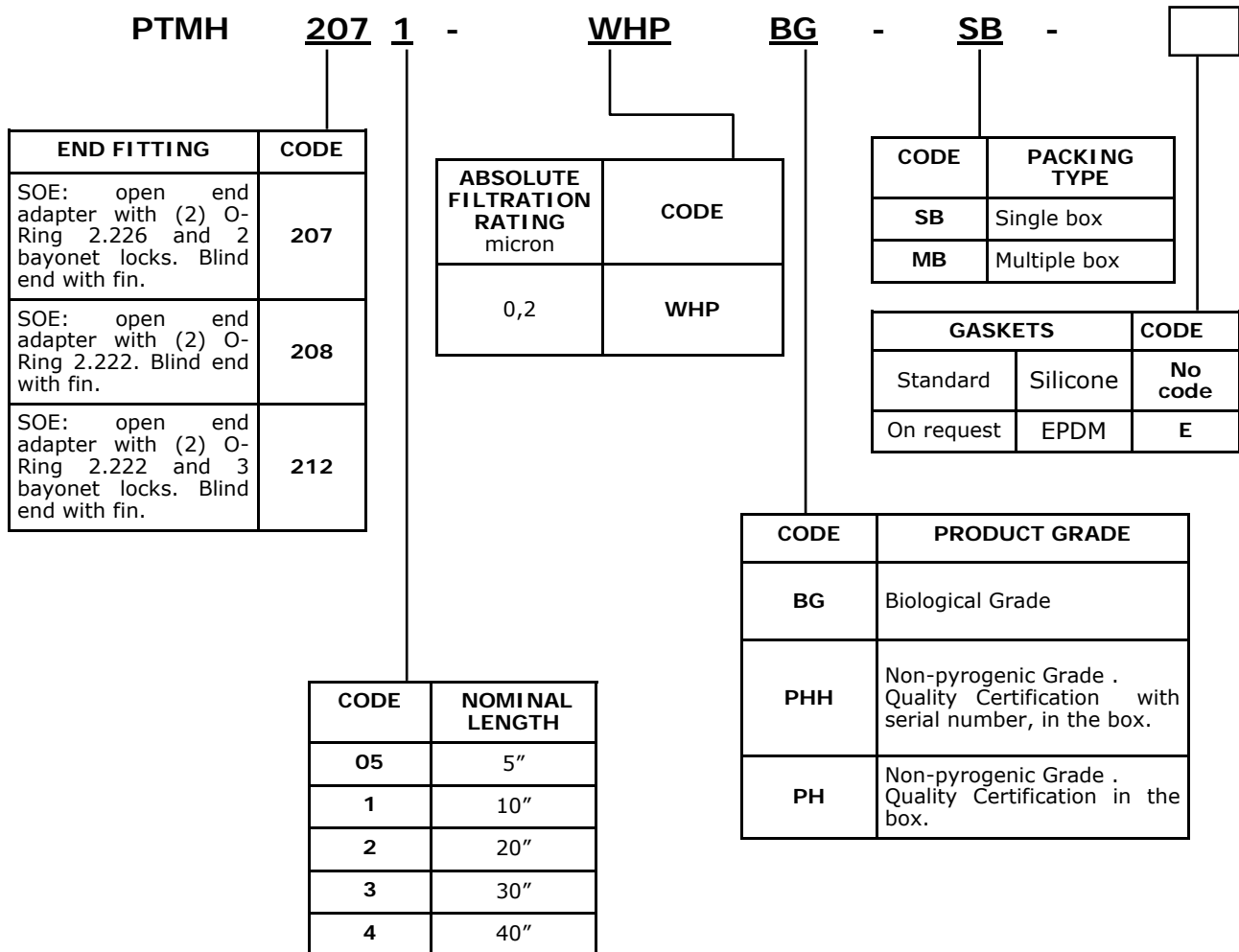
1- BACTERIAL RETENTION TEST as per ASTM F838.

2- The integrity is verified by DIFFUSION TEST using an aqueous solution of isopropyl alcohol (IPA 60/40 V/V) as wetting agent.

AIR FLOW RATE FOR 10" CARTRIDGE



STERYTEMP Plus ORDERING INFORMATION



Data contained in this bulletin are informative and subject to change without notice. User is responsible for determining whether the product is fit for particular purpose and suitable for User's method of application.



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