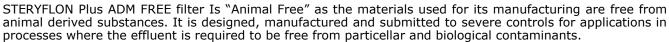


# STERYFLON Plus ADM FREE

- Materials free from substances of animal origin (ADM FREE- Animal Derived Materials)
- · Intrinsecally Hydrophobic PTFE membrane
- High permeability versus gas
- · Thermic cycles resistant
- Repeatedly steamable in situ or in autoclave
- Thermowelded construction
- Food contact materials according to EU and FDA requirements
- Bio-Safety per USP-Plastics
- Validation Guide available on request



The expanded PTFE membrane, intrinsically hydrophobic, allows superior performances both in gas filtration and non-acqueos liquid filtration. Bio-tech pharmaceutical, electronic, food & beverage industries can rely on a product with high standard of quality suitable to solve contamination issues on critical applications. Furthermore, the complete absence of animal derived substances makes it suitable for the newest and even more increasing market requirements.

STERYFLON Plus ADM FREE is manufactured within a controlled environment and each cartridge is integrity tested and is validated for bacterial retention correlated with microbiological challenge test. The retention is checked on regular sampling.

### **MATERIALS OF CONSTRUCTION**

Filter media	PTFE membrane	
Upstream supports	polypropylene	
Downstream supports	polypropylene	
Internal Core	polypropylene	
External Cage	polypropylene	
End caps / Adapters	polypropylene	

### **FOOD-SAFETY**

STERYFLON Plus ADM FREE filter element materials meet (EU) regulation 10/2011 and its amendments, regulations (EC) 1935/2004 and 1895/2005.

### **BIO-SAFET**

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).

QUALITY STANDARDS

Produced under a certified Quality System to guarantee traceability of manufacturing records and integrity testing

results.

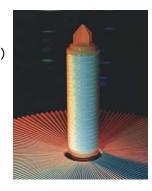
## **OPERATING CONDITIONS**

- max. continuous temperature of fermentation inlet and exhaust air	70 °C	
- max. continuous temperature for vent filter in recirculation loop	83 °C	
- max. cumulative time of steam sterilization	150 hours at 140 °C with cycles of 30 minutes	
- sanitization with chemicals	can be sanitized by standard chemical agents	
- max. differential pressure	5,0 bar at 25 °C	
- recommended change out differential pressure	2,0 bar at 25 °C	

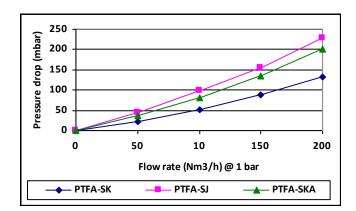
CODE	ABSOLUTE FILTRATION RATING		3) BACTERIAL RETENTION >10 <sup>7</sup> CFU/cm <sup>2</sup>	ACCEPTABLE LIMIT FOR INTEGRITY TEST
	IN LIQUID	IN DRY GAS	>10 CFO/CIII	FOR 10" CARTRIDGE
SJ	0,1 μm	< 0,01 µm	Acheleoplasma laidlawii in liquid	1) ≤ 25 ml/min @ 1,0 bar
SK	0,2 μm	< 0,01 µm	B. Diminuta in liquid / Batteriofago T1 in aerosol	1) ≤ 12 ml/min @ 0,8 bar
SKA	0,2 μm	< 0,01 µm	Brevundimonas diminuta in liquid	2) ≤ 16 Nml/10min @ 2,5 bar

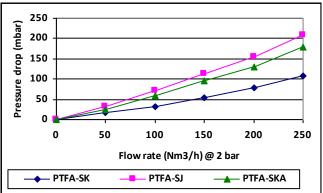
# Note:

- 1- The integrity is verified by DIFFUSION TEST using an aqueous solution of isopropyl alcohol (IPA 60/40 V/V) as wetting liquid.
- The integrity is verified by WATER FLOW INTRUSION TEST.
- 3- Cartridges are validated for retention of the microorganism reported in the table according to ASTM F838.

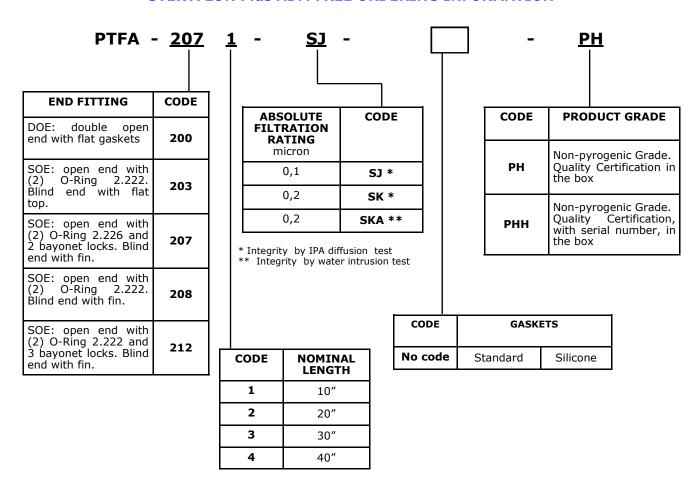


# **AIR FLOW RATE FOR 10" CARTRIDGE**





# STERYFLON Plus ADM FREE 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.

