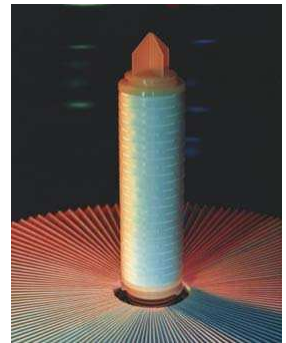


## STERYFLON Plus

- Intrinsically Hydrophobic PTFE membrane
- High permeability versus gas
- Thermic cycles resistant
- Repeatedly steamable in situ or in autoclave
- Thermowelded construction
- FDA-listed materials per CFR21
- Bio-Safety per USP-Plastics
- Validation Guide available on request



STERYFLON Plus is a filter element designed, manufactured and submitted to severe controls for applications in processes where the effluent is required to be free from particellar and biological contaminants.

The expanded PTFE membrane, intrinsically hydrophobic, allows superior performances both in gas filtration and non-aqueous 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.

STERYFLON is manufactured within a controlled environment and each cartridge is integrity tested and is validated for bacterial retention correlated with microbiological challenge test.

### MATERIALS OF CONSTRUCTION

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

### FOOD-SAFETY

STERYFLON Plus filter elements meet regulation (EC) 1935/2004 for indirect food contact.

### 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).

### 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		
SH	0,1 µm	< 0,01 µm	Acheleoplasma laidlawii in liquid	1) ≤ 12 ml/min @ 1,3 bar
SL	0,2 µm	< 0,01 µm	Batteriofago T1 in aerosol	1) ≤ 12 ml/min @ 0,8 bar
SLA	0,2 µm	< 0,01 µm	Brevundimonas diminuta in liquid	2) ≤ 16 Nml/10min @ 2,5 bar

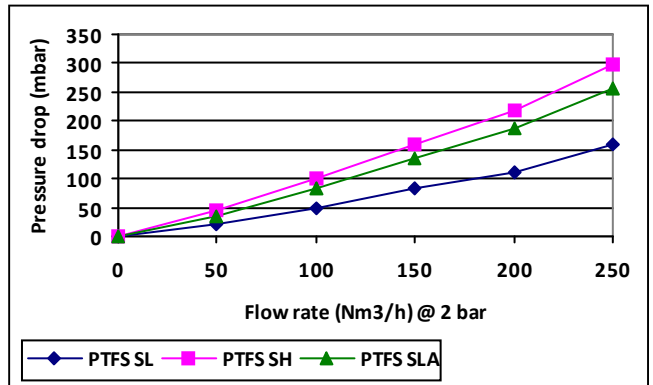
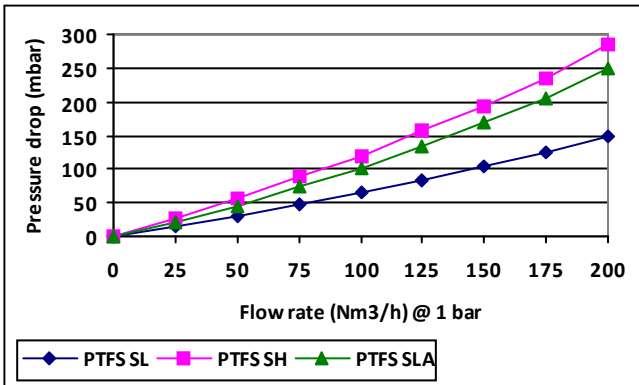
Note:

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

2- 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 F838-05.

## AIR FLOW RATE FOR 10" CARTRIDGE



## STERYFLON Plus ORDERING INFORMATION

**PTFS - 207 1 - SL - [ ] - PH**

END FITTING	CODE
DOE: double open end with flat gaskets	<b>200</b>
SOE: open end with (2) O-Ring 2.222. Blind end with flat top.	<b>203</b>
SOE: open end with (2) O-Ring 2.226 and 2 bayonet locks. Blind end with fin.	<b>207</b>
SOE: open end with (2) O-Ring 2.222. Blind end with fin.	<b>208</b>
SOE: open end with (2) O-Ring 2.222 and 3 bayonet locks. Blind end with fin.	<b>212</b>

ABSOLUTE FILTRATION RATING micron	CODE
0,1	<b>SH *</b>
0,2	<b>SL *</b>
0,2	<b>SLA **</b>

\* Integrity by IPA diffusion test  
 \*\* Integrity by water intrusion test

CODE	PRODUCT GRADE
<b>No code</b>	Biological Grade
<b>PH</b>	Non-pyrogenic Grade. Quality Certification in the box
<b>PHH</b>	Non-pyrogenic Grade. Quality Certification, with serial number, in the box

CODE	NOMINAL LENGTH
<b>05</b>	5"
<b>1</b>	10"
<b>2</b>	20"
<b>3</b>	30"
<b>4</b>	40"

CODE	GASKETS		END FITTING
	Standard	EPDM	
<b>No code</b>	Standard	EPDM	200
<b>T</b>	On request	Teflon	All the others
<b>No code</b>	Standard	Silicone	
<b>V</b>	On request	Viton	
<b>F</b>	On request	FEP	207

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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