

STERYFLON Plus

- Intrinsecally 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-acqueos liquid filtration. Bio-tech pharmaceutical, electronic, food & beverage industries can roly 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. The retention is checked on regular sampling.

MATERIALS OF CONSTRUCTION

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

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

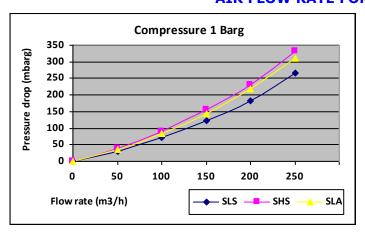
| - max. continuous temperature of fermentation inlet and exhaust air | 70 °C | |
|---|---|--|
| - max. continuous temperature for vent filter in recirculation loop | 83 °C | |
| - max. cumulative time of steam sterilization | 150 hours at 140 °C with cycles of 30 minutes | |
| - sanitization with chemicals | 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 | |

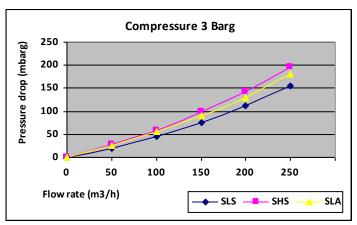
| CODE | ABSOLUTE FILTRATION RATING | | 3) BACTERIAL RETENTION >10 ⁷ CFU/cm ² | ACCEPTABLE LIMIT FOR INTEGRITY TEST |
|--|---|----------------------------------|---|-------------------------------------|
| | IN LIQUID | IN DRY GAS | >10 CF0/CIII | FOR 10" CARTRIDGE |
| SH 0,1 μm | | < 0,01 µm | Acheleoplasma laidlawii in liquid | 1) ≤ 25 ml/min @ 1,0 bar |
| SL | 0,2 μm < 0,01 μm B. Diminuta in liquid / Batteriofago T1 in aerosol | | 1) ≤ 12 ml/min @ 0,8 bar | |
| SLA 0,2 μm < 0,01 μm Brevundimonas dim | | Brevundimonas diminuta in liquid | 2) ≤ 16 Nml/10min @ 2,5 bar | |

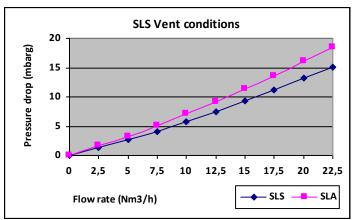
- 1– The integrity is verified by DIFFUSION TEST using an aqueous solution of isopropyl alcohol (IPA 60/40 V/V) as wetting liquid.

 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.

AIR FLOW RATE FOR 10" CARTRIDGE

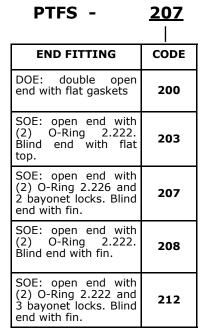






STERYFLON Plus ORDERING INFORMATION

SL



| ABSOLUTE FILTRATION RATING micron | CODE |
|--|--------|
| 0,1 | SH * |
| 0,2 | SL * |
| 0,2 | SLA ** |

| CODE | PRODUCT GRADE | |
|---------|---|--|
| No code | Biological Grade | |
| PH | Non-pyrogenic Grade. Quality Certification in the box | |
| РНН | Non-pyrogenic Grade. Quality Certification, with serial number, in the box | |

| CODE | CODE NOMINAL LENGTH | |
|------|---------------------|--|
| 05 | 5″ | |
| 1 | 10" | |
| 2 | 20″ | |
| 3 | 30" | |
| 4 | 40" | |

| CODE | GASKETS | | FITTING | |
|-------------------------|------------|----------|----------------|--|
| No code | Standard | EPDM | 200 | |
| Т | On request | Teflon | | |
| No code | Standard | Silicone | | |
| V | On request | Viton | All the others | |
| E | On request | EPDM | | |
| F On request FEP | | 207 | | |

CACKETS

<u>PH</u>

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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CODE

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