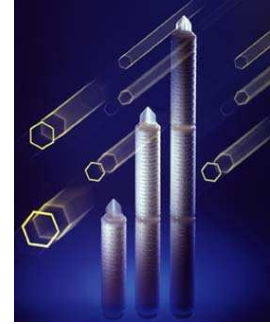


## STERYFLUS TSP MULTI-LAYERS

- Integrity testable in situ
- Repeatedly steamable in situ or in autoclave
- Sanitizable
- Thermowelded construction
- EC-listed materials for Food contact
- FDA-listed materials per CFR21
- Bio-Safety per USP-Plastics



STERYFLUS TSP MULTI-layers is utilized in the pharmaceutical and food & beverage general application. The biological grade PH, prefluxed with non-pyrogenic water and with certification of quality reporting the serial number, is utilized in critical applications.

The filter media is constituted by PES (Hydrophilic Polyethersulfone) absolute filtration rating membrane; upstream borosilicate microfibers layer provides prefiltration to protect the membrane; the depth matrix of the borosilicate media retains particle matters as well as deformable contaminants like colloids, granting the cartridges with longer service life.

Manufacturing is completed in a controlled environment; each cartridge is integrity tested and the limits of acceptability are monitored on regular basis by bacteria challenge test.

### MATERIALS OF CONSTRUCTION

<b>Filter media</b>	PES membrane + borosilicate microfiber
<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

STERYFLUS TSP MULTILAYERS filter element materials meet (EU) regulation 10/2011 and its amendments, regulations (EC) 1935/2004 and 1895/2005.

### BIO-SAFETY

Filter media and components pass USP Biological Reactivity and Chemical-Physical tests for CLASS VI plastics.

Specific for "PH" grade: 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.

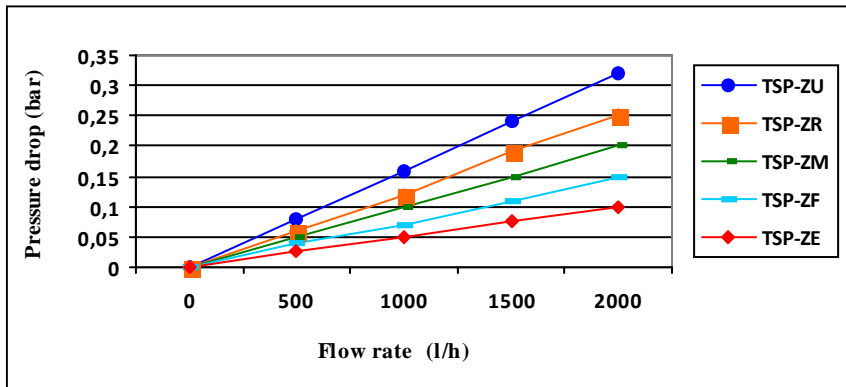
### OPERATING CONDITIONS

- max. continuous temperature	65 °C
- max. cumulative time of steam sterilization	20 hours at 125 °C or 40 hours at 121 °C with cycles of 30 minutes
- sanitization with hot water	80 °C max
- sanitization with chemicals	can be sanitized by standard chemical agents
- max. differential pressure	5,0 bar at 25 °C - 1,7 bar at 80 °C
- recommended change out differential pressure	2,0 bar at 25 °C
- recommended rinse up volume	3 liters/10" cartridge

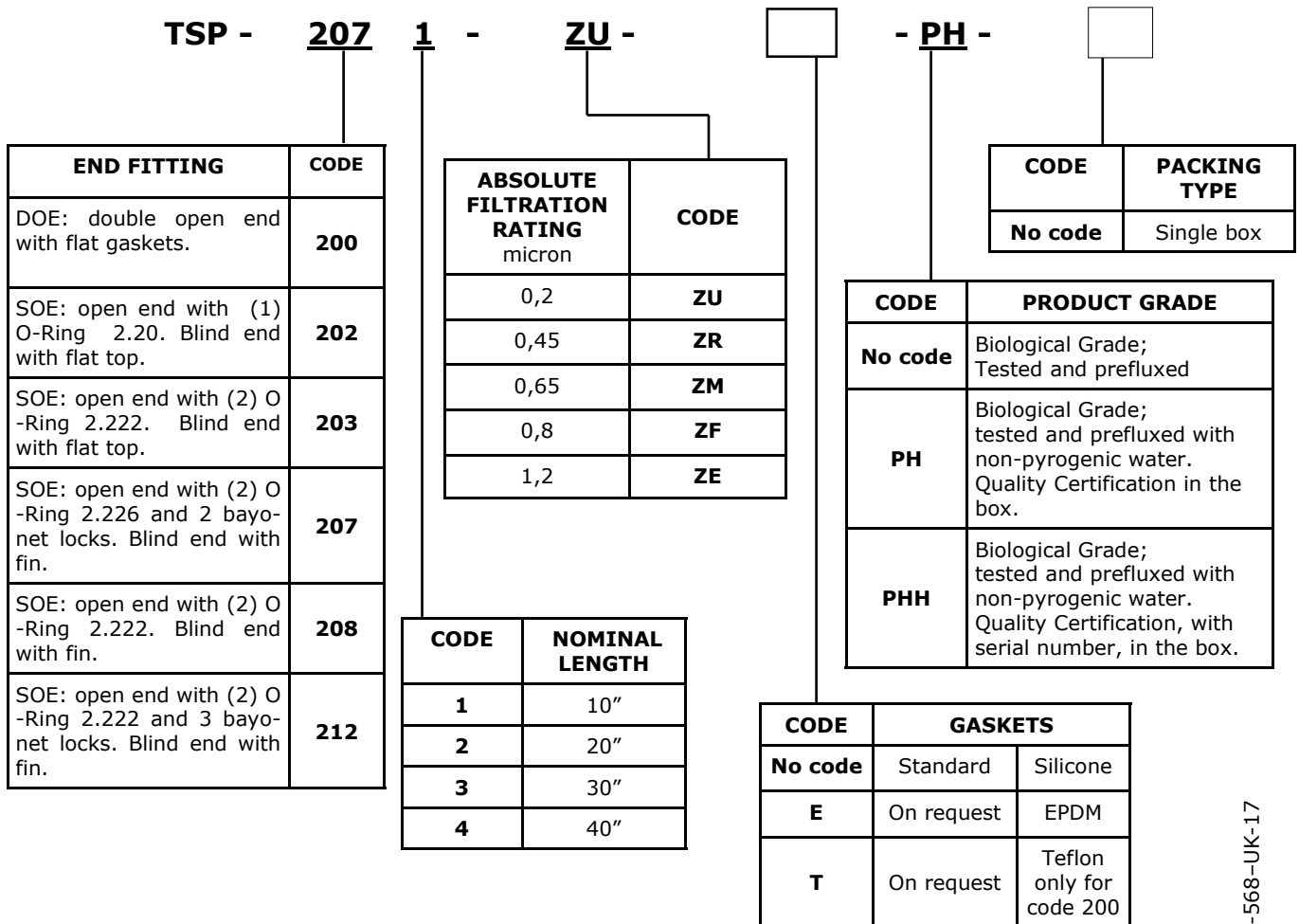
CODE	ABSOLUTE FILTRATION RATING IN LIQUIDS	BACTERIAL RETENTION >10 <sup>7</sup> CFU/cm <sup>2</sup>	ACCEPTABLE LIMIT FOR DIFFUSION TEST WITH WATER FOR 10" CARTRIDGE (ml/min)
ZU	0,2 µm	Brevundimonas diminuta	≤ 14 @ 2,3 bar
ZR	0,45 µm	Serratia marcescens	≤ 10 @ 1,7 bar
ZM	0,65 µm	N.A	≤ 20 @ 1,1 bar
ZF	0,8 µm	N.A	≤ 25 @ 0,9 bar
ZE	1,2 µm	N.A	≤ 25 @ 0,8 bar

\*as per ASTM F838

## WATER FLOW RATE FOR 10" CARTRIDGE



## STERYFLUS TSP MULTILAYER 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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