

# STERYKLEAR KSE

- Easy integrity testable in situ
- High effective filtering area with SE-TECH technology
- Repeatedly steamable in situ and in autoclave
- Sanitizable
- Thermowelded construction
- EC-listed materials for Food contact
- FDA-listed materials per CFR21
- Bio-Safety per USP—Plastics
- Validation Guide available on request



STERYKLEAR KSE filter elements incorporate SE-TECH tecnology which allows to achieve better filtration results from the membranes; the design optimises the flow distribution between the filter media and the internal core to avoid restrictions and to exploit the full area of the cartridge to generate higher throughput and to increase the life of the filter.

STERYKLEAR KSE is utilized as final sterilizing filter in pharmaceutical and food & beverage general application; PH and PHH grade, prefluxed with non-pyrogenic water and with certification of quality, are utilized in critical applications. The cartridge, realized with polyether components can operate in continuous at temperature of 80°C.

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**

Filter media	Asymmetric PES membrane
Upstream supports	polyester
Downstream supports	polyester
Internal Core	polypropylene
External Cage	polypropylene
End caps / Adapters	polyester

### **FOOD-SAFETY**

STERYKLEAR KSE 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" and "PHH" 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**

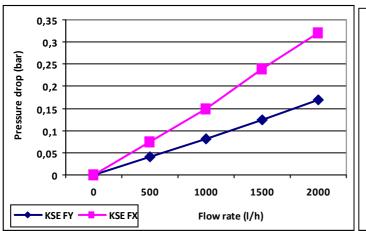
Produced under a certified Quality System to guarantee traceability of manufacturing records and integrity testing results.

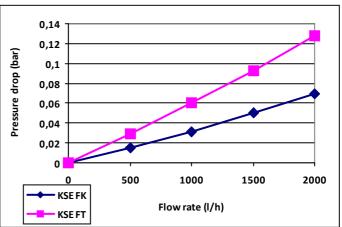
## **OPERATING CONDITIONS**

- max. continuous temperature	80 °C
- max. cumulative time of steam sterilization	13 hours at 125 °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
- recommended change out differential pressure	2,0 bar at 25 °C
- recommended rinse up volume	3 liters/cartridge 10"

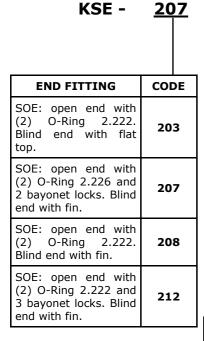
CODE	ABSOLUTE FILTRATION RATING IN LIQUIDS	BACTERIAL RETENTION OF MICRO-ORGANISM >10 <sup>10</sup> CFU/ 10" CARTRIDGE*	ACCEPTABLE LIMIT FOR DIFFUSION FLOW TEST WITH WATER FOR 10" CARTRIDGE (ml/min)
FX	0,1 μm	Acholeplasma laidlawii	≤ 30 @ 3,5 bar
FY	0,2 μm	Brevundimonas diminuta	≤ 26 @ 2,7 bar
FT	0,45 μm	Serratia marcescens	≤ 16 @ 1,7 bar
FK	0,65 μm	Leuconostoc oenos	≤ 25 @ 1,1 bar
*as per ASTM F838-05			

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





# STERYKLEAR KSE ORDERING INFORMATION



ABSOLUTE FILTRATION RATING micron	CODE
0,1	FX
0,2	FY
0,45	FT
0,65	FK

CODE		
		Γ
E		

CODE	NOMINAL LENGTH
1	10"
2	20″
3	30″
4	40"

CODE	GASKETS	
No code	Standard	Silicone
E	On request	EPDM
V	On request	VITON

CODE	PACKING TYPE	
SB	Single box	
МВ	Multiple box	

CODE	PRODUCT GRADE
BG	Biological Grade; tested and prefluxed .
BQ	Biological Grade; tested and prefluxed. Quality Certification in the box.
PH	Biological Grade; tested and prefluxed with non-pyrogenic water. Quality Certification in the box
РНН	Biological Grade; tested and prefluxed with non-pyrogenic water. Quality Certification, with serial number, in the box

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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