STERINYL ADM FREE—KLEA

- Materials free from substances of animal origin (ADM FREE—Animal Derived Materials)
- Food contact materials, according to EU and FDA requirements
- Bio-Safety and composition compliance according to USP requirements for plastics
- Low filter extractables even with solvents
- Easy integrity testable in situ
- Repeatedly steamable in situ and in autoclave
- Thermowelded construction
- Validation Guide available on request

STERINYL ADM FREE filter element is "Animal Free" as the materials used for its manufacturing are free from animal derived substances. It is designed and manufactured to satisfy and assure high quality and consistent performances in critical applications.
STERINYL ADM FREE cartridge includes Nylon 6,6 membrane at controlled porosity and provides high efficiency in bacteria retention.
The membrane is pleated with support and drainage layers in polyester which give high endurance versus thermal sterilization and hydraulic pulsation stress.
The intrinsically water wettability of nylon and polyester allows easy integrity testability. Manufacturing is completed in a controlled environment; each filter is integrity tested.
STERINYL ADM FREE filter element 0.1 micron and 0.2 micron are available with single and double membrane layer.

MATERIALS OF CONSTRUCTION

Filter media	nylon 6,6
Upstream supports	polyester
Downstream supports	polyester
Internal Core	polypropylene
External Cage	polypropylene
End caps / Adapters	polyester

FOOD-SAFETY

STERINYL ADM FREE 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 CLASS VI Biological Reactivity and Chemical-Physical tests for USP 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.

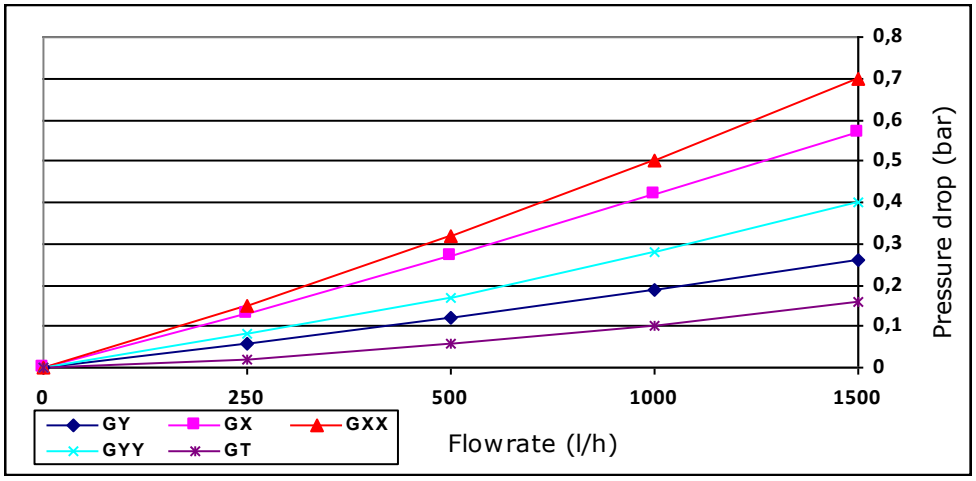
OPERATING CONDITIONS

- max. continuous temperature	80 °C
- max. cumulative time of steam sterilization	5 hours at 140°C / 13 hours at 125°C / 20 hours at 121 °C
- 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—2,5 bar 80 °C—0,3 bar 135 °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 $>10^{10}$ CFU/ 10" CARTRIDGE*	ACCEPTABLE LIMIT FOR DIFFUSION FLOW TEST WITH WATER FOR 10" CARTRIDGE (ml/min)
GX**	0,1 µm	Hydrogenophaga pseudoflava	≤ 15 @ 2,8 bar
GXX**	0,1 µm double layer	Hydrogenophaga pseudoflava	≤ 15 @ 2,8 bar
GY	0,2 µm	Brevundimonas diminuta	≤ 16 @ 2,1 bar
GYY	0,2 µm double layer	Brevundimonas diminuta	≤ 16 @ 2,1 bar
GT	0,45 µm	Serratia marcescens	≤ 16 @ 1,5 bar
GK	0,65 µm	Leuconostoc oenos	≤ 18 @ 0,9 bar

*as per ASTM F838
** bacterical retention with Acholeplasma laidlawii ≥ 10^8

WATER FLOW RATE FOR 10" CARTRIDGE



STERINYL ADM FREE KLEA ORDERING INFORMATION

KLEA - 207 1 - GY - PH - [ ] - [ ]

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

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

ABSOLUTE FILTRATION RATING micron	CODE
0,1	**GX**
0,1	**GXX**
0,2	**GY**
0,2	**GYY**
0,45	**GT**
0,65	**GK**

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

CODE	PACKING TYPE
No code	Single box

CODE	GASKETS	
No code	Standard	Silicone
E	On request	EPDM
Z	Only D.O.E.	Soft teflon

DS-KLEA-559-EN-19

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