

## STERINYL MINI CARTRIDGES

### High performance nylon 6,6

- Easy integrity testable in situ
- Repeatedly steamable in situ and in autoclave
- Thermowelded construction
- EC-listed materials for Food contact
- FDA-listed materials per 21 CFR
- Bio-Safety per USP—Plastics
- Low filter extractables even with solvents
- Validation Guide available on request



STERINYL Mini filter element is a complementary compound to Sterinyl series suitable to filter small batches. Sterinyl Mini is manufactured with Nylon 6,6 that has a controlled porosity that 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 stress.

The intrinsically water wettability of nylon and polyester allows easy integrity testability.

Manufacturing is performed in a controlled environment; each filter is integrity tested.

#### MATERIALS OF CONSTRUCTION

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

#### FOOD-SAFETY

STERINYL Mini 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.

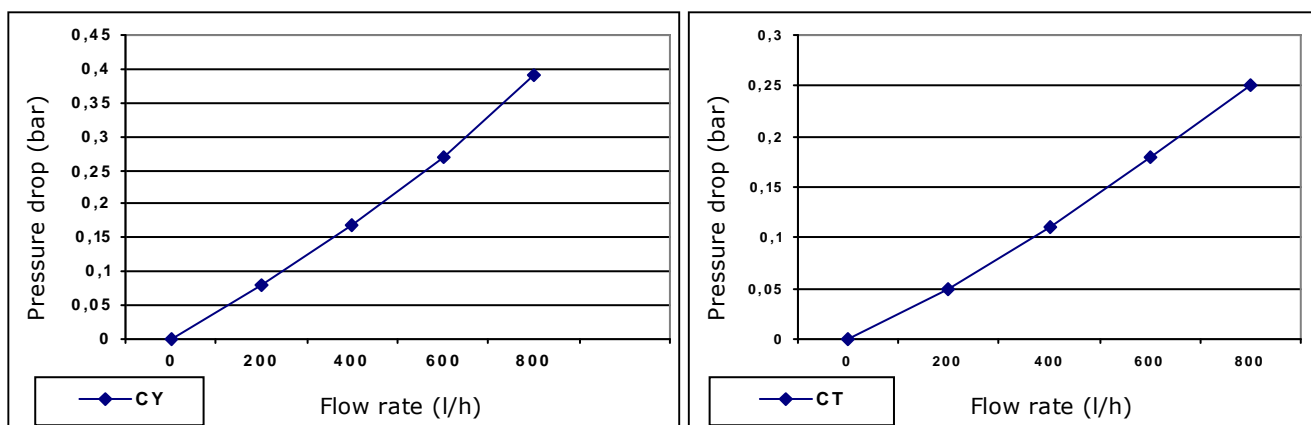
#### OPERATING CONDITIONS

<b>- max. continuous temperature</b>	80 °C
<b>- max. cumulative time of steam sterilization</b>	10 hours at 125 °C with cycles of 60 minutes /20 hours at 121 °C
<b>- sanitization with hot water</b>	80 °C max
<b>- sanitization with chemicals</b>	Can be sanitized by standard chemical agents
<b>- max. differential pressure</b>	5,0 bar at 25 °C—2,5 bar 80 °C—0,3 bar 135 °C
<b>- recommended change out differential pressure</b>	2,0 bar at 25 °C
<b>- recommended rinse up volume</b>	2 liters

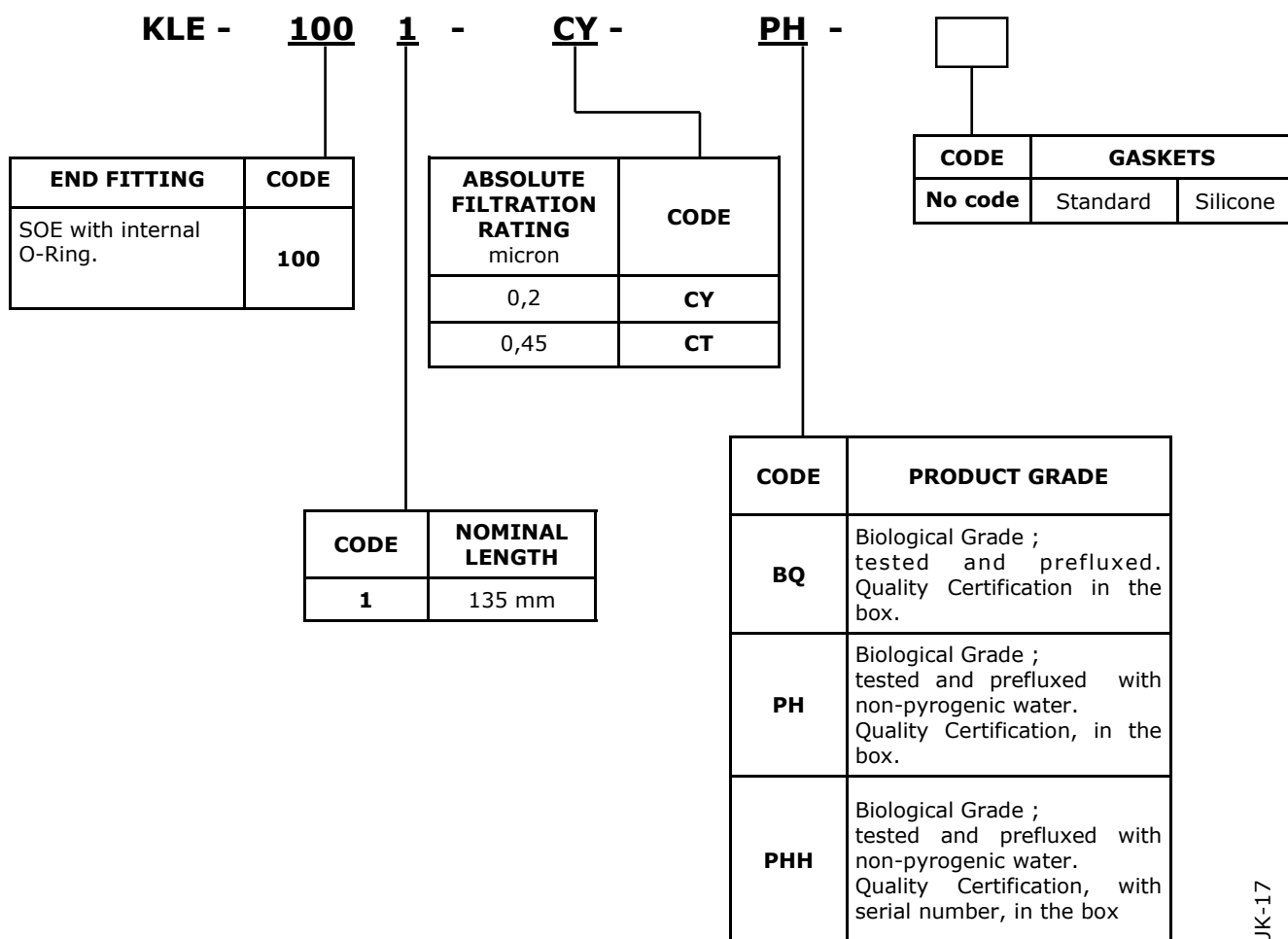
CODE	ABSOLUTE FILTRATION RATING IN LIQUIDS	BACTERIAL RETENTION OF MICRO-ORGANISM >10 <sup>10</sup> CFU PER CARTRIDGE *	ACCEPTABLE LIMIT FOR DIFFUSION FLOW TEST WITH WATER (ml/min)
CY	0,2 µm	Brevundimonas diminuta	≤ 8 @ 2,1 bar
CT	0,45 µm	Serratia marcescens	≤ 8 @ 1,5 bar

\*as per ASTM F838

## WATER FLOW RATE



## STERINYL MINI 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.



**Bea Technologies Spa** Via Newton, 4 - 20016 Pero (Milano) ITALY  
Tel +39 02 339271 FAX +39 02 3390713 e-mail: [info@bea-italy.com](mailto:info@bea-italy.com)  
web: [www.bea-italy.com](http://www.bea-italy.com)