

## QUALIKAP QKP-S

### PES capsule filters

- Testable in situ
- Sterilizable in autoclave
- Sanitizable
- Thermowelded assembly
- EC-listed materials for food contact
- FDA-listed materials per CFR21
- Extractables as per USP for plastic materials
- Validation Guide available
- Low extractable



QUALIKAP QKP-S capsules are especially designed to be used as sterilizable final filter for small batches in pharma and food applications. QUALIKAP QKP-S are fitted with a pleated membrane filter element, whose polyethersulfone asymmetric porosity guarantees enhanced flow rate and a wide chemical compatibility both for acid and basic solutions.

Typical applications are alcoholic solutions, ultra pure water, vaccine, physiological solutions, ophthalmic liquids and lab batch purification process, etc.

The manufacturing is done in a controlled environment; each filter element is tested to verify the integrity. Each capsule is supplied with conformity test certificate showing the lot.

#### MATERIALS OF CONSTRUCTION

<b>Membrane</b>	asymmetric PES membrane
<b>Upstream drainage layers</b>	Polyester
<b>Downstream drainage layers</b>	Polyester
<b>Core and Cage</b>	polypropylene
<b>Outer Shell</b>	polypropylene
<b>Terminals</b>	polypropylene

#### FOOD-SAFETY

QUALIKAP-QKP-S capsules meet (EU) regulation 10/2011 and its subsequent amendments and regulations (EC) 1935/2004 and 1895/2005.

#### BIO-SAFETY AND EXTRACTABLES

- Materials are compliant to USP-VI CLASS toxicological requirements and USP-Plastic Materials chemical and physical requirements.
- Capsule filters meet USP "Water for injection" requirements for endotoxin particle release; the bacterial endotoxin are determined using LAL Test.
- Extractable NVR (gravimetric) after autoclave  $\leq 2$  mg.
- TOC and conductivity according USP "Purified water" and "Water for Injection" requirements.

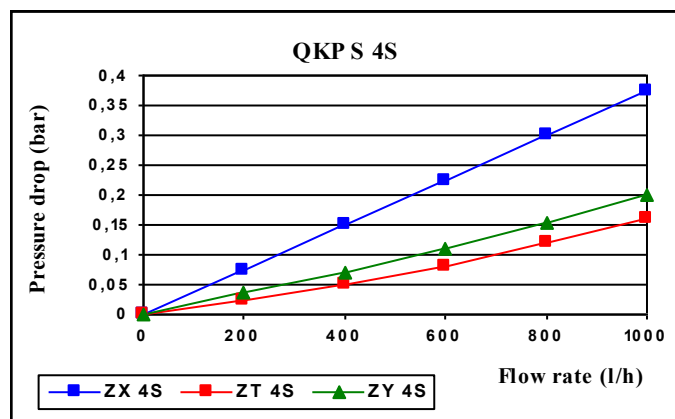
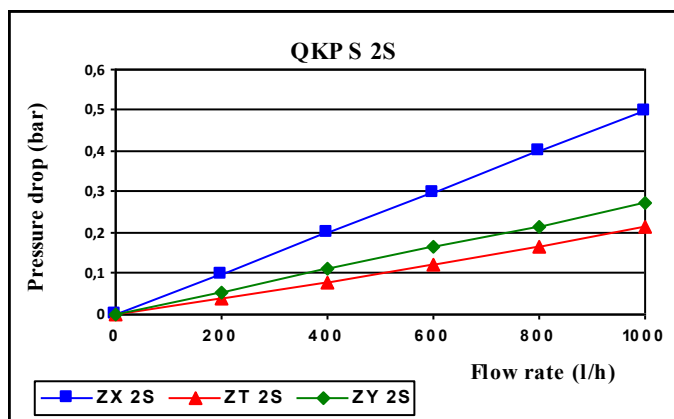
#### RECOMMENDED OPERATING CONDITIONS

- max. continuous temperature	40 °C
- max. cumulative time of steam sterilization (no in line sterilization available)	16 hours at 125 °C or 8 hours at 135 °C (30' cycle)
- max. pressure	5 bar at 40 °C
- chemical sanitization	compatible with a wide range of sanitizers
- forward flow max. differential pressure	4,5 bar at 40 °C
- reverse flow max. differential pressure	1,0 bar at 40 °C
- recommended pressure drop for changeover	2,0 bar at 40 °C
- in situ recommended flushing volume	1 liter

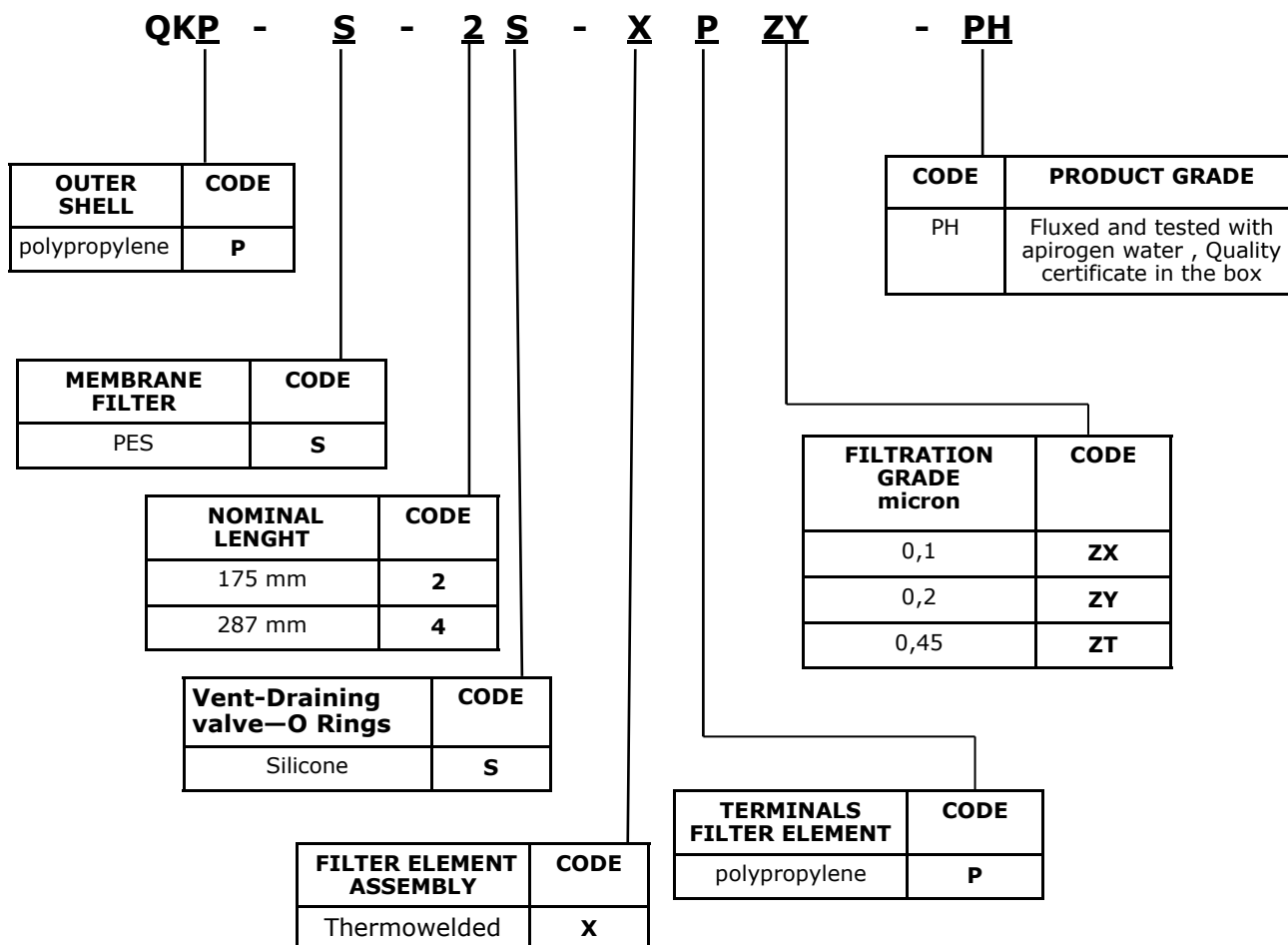
CODE	ABSOLUTE FILTRATION GRADE IN LIQUIDS	BACTERIAL REDUCTION CHARGE $>10^7$ CFU/cm <sup>2</sup> *	ACCEPTANCE LIMIT FOR DIFFUSION TEST (ml/min)
ZX	0,1 µm	Acholeplasma Laidlawii	$\leq 9.0$ @ 3,5 bar for size 2
			$\leq 18.0$ @ 3,5 bar for size 4
ZY	0,2 µm	Brevundimonas Diminuta	$\leq 8.0$ @ 2,8 bar for size 2
			$\leq 16.0$ @ 2,8 bar for size 4
ZT	0,45 µm	Serratia marcescens	$\leq 7.5$ @ 1,7 bar for size 2
			$\leq 15.0$ @ 1,7 bar for size 4

\* according ASTM F838

## WATER FLOW RATE CHARTS



## QUALIKAP QKP-S ORDERING INFORMATION



- Max diameter (valves included): 117 mm
- Tri-clamp connections 1 1/2"

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.  
 For the type of liquids and gases that can be used, contact Bea Technologies.



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