

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

Membrane	asymmetric PES membrane
Upstream drainage layers	Polyester
Downstream drainage layers	Polyester
Core and Cage	polypropylene
Outer Shell	polypropylene
Terminals	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 ≤ 2 mg.
- TOC and conductivity according USP "Purified water" and "Water for Injection" requirements.

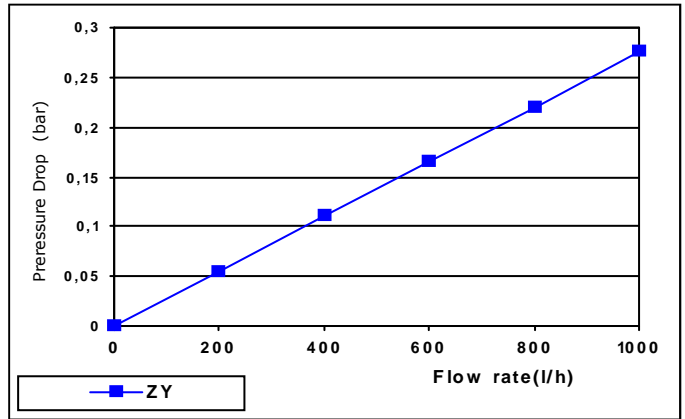
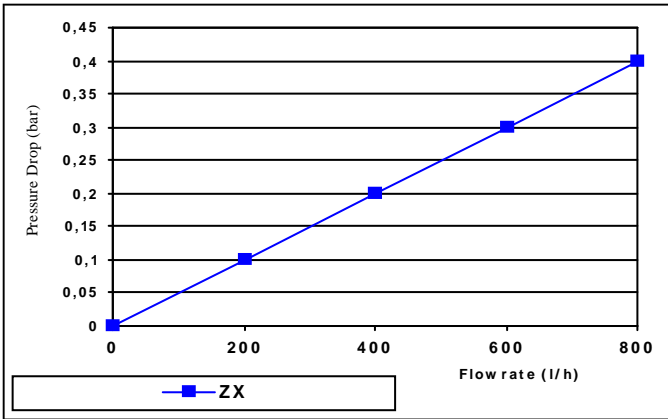
RECOMMENDED OPERATING CONDITIONS

- max. continuous temperature	70 °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 - 5,5 bar at 25 °C
- chemical sanitization	compatible with a wide range of sanitizers
- forward flow max. differential pressure	4,5 bar at 40 °C - 1,0 bar at 80 °C
- reverse flow max. differential pressure	3,5 bar at 40 °C
- recommended pressure drop for changeover	2,0 bar at 25 °C
- in situ recommended flushing volume	1 liter

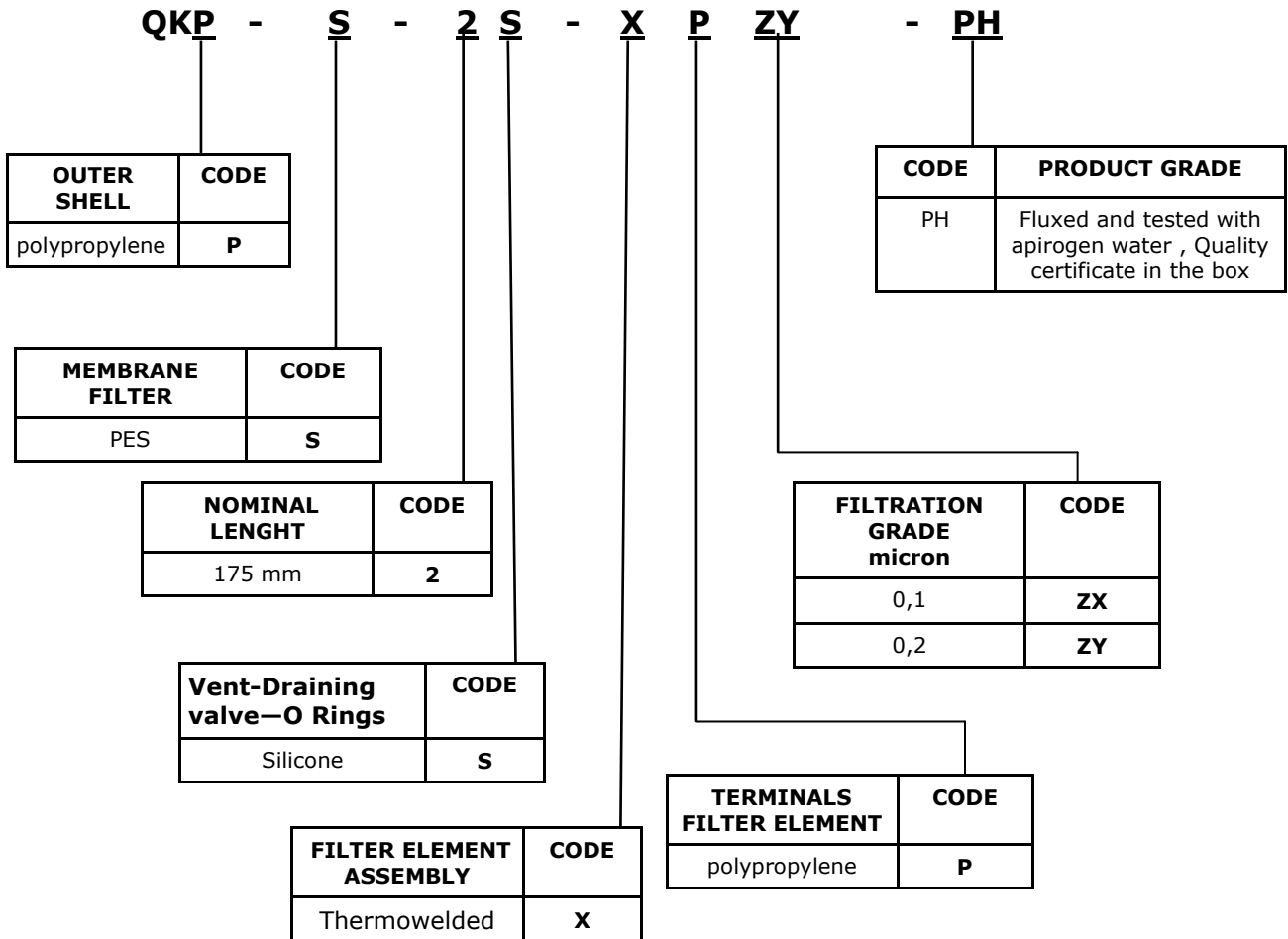
CODE	ABSOLUTE FILTRATION GRADE IN LIQUIDS	BACTERIAL REDUCTION CHARGE $>10^7$ CFU/cm ² *	ACCEPTANCE LIMIT FOR DIFFUSION TEST (ml/min)
ZX	0,1 µm	Acholeplasma Laidlawii	≤ 9.0 @ 3,5 bar
ZY	0,2 µm	Brevundimonas Diminuta	≤ 8.0 @ 2,8 bar

* according ASTM F838-05

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.



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