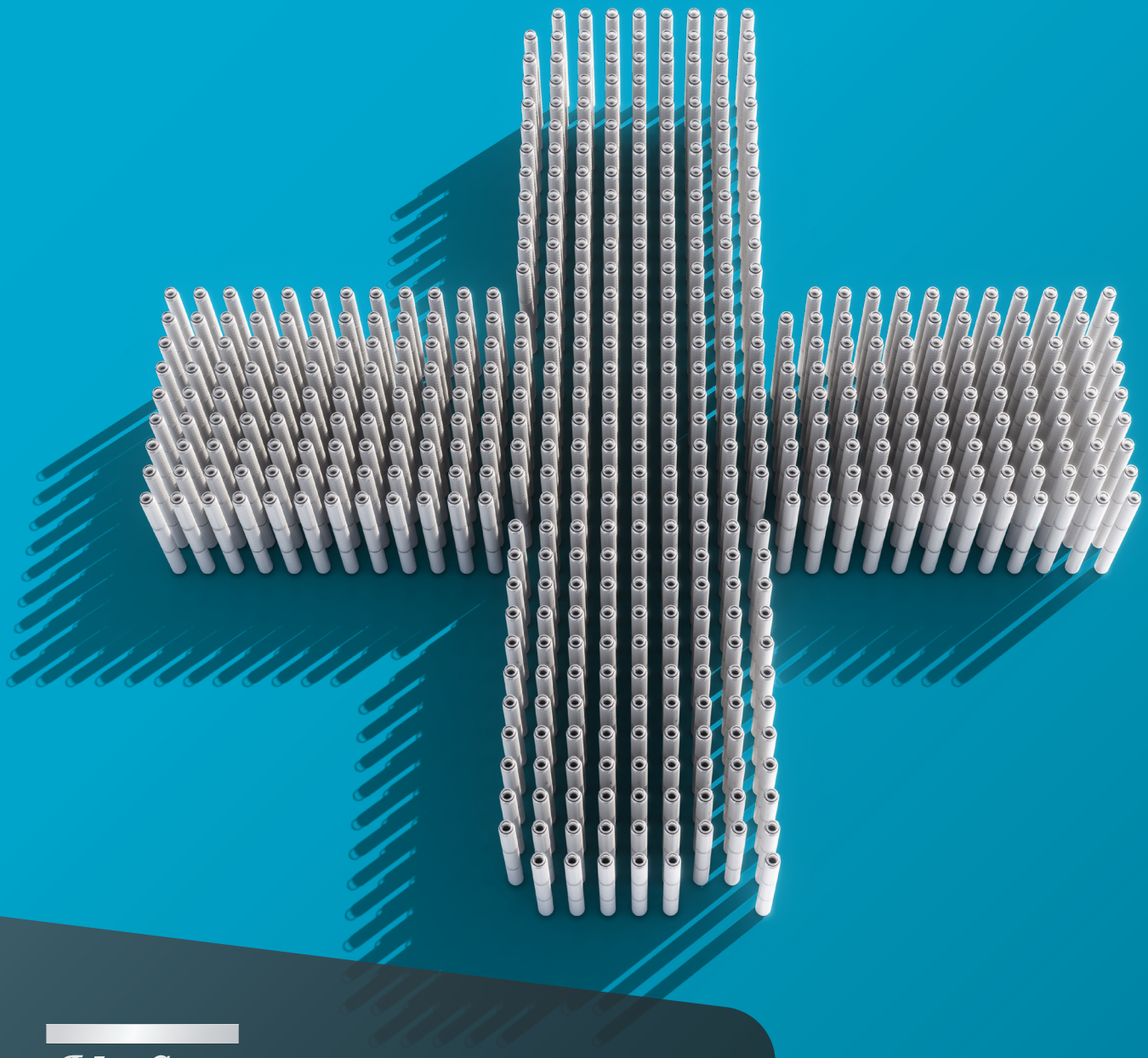


Atlas Copco

SME-X+ P

PLUS series pleated PES membrane filters pharmaceutical grade

SME-X⁺ series pleated PES membrane filters pharmaceutical grade

Product description

Introduction

The Atlas Copco SME-X⁺ P range has been designed for use in bioprocessing and pharmaceutical applications. It provides safe, reliable and efficient bioburden control and sterilization of valuable liquids used in Food & Beverage, Pharmaceutical and Chemical industries. The filters effectively retain particles and micro-organisms through a double layer asymmetric, hydrophilic PES membrane characterized by low extractable and protein binding.

Devices

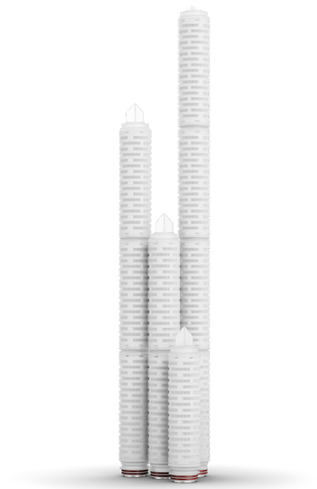
SME-X⁺ P filters are available in a wide range of cartridges, mini cartridges and capsules. All filters incorporate the same media and identical materials of construction, eliminating the need to requalify filter units as processes are scaled up.

Compatibility

SME-X⁺ P filter's hardware features polypropylene core and cage, with a combination of nylon end supports and PET support layers to aid wettability. Thermal welding techniques seal all the components therefore optimizing device integrity, as well as assuring a broad chemical compatibility with a large number of solvents, acids and bases. The construction guarantees a small extractable footprint. All jointed surfaces are assembled by the use of heat sealing technology. No resins or binders are used in the manufacture of the filter and no surfactants are added to aid wetting.

Documentation

SME-X⁺ P filters are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. A Technical Report is available for compliance with regulatory requirements.
All the materials used comply with the European Union Regulation (EC) No. 1935/2004 as well as the Regulation (EU) No. 10/2011. concerning plastic materials and articles intended to come into contact with foodstuffs. These guidelines for plastics allow the use in food and beverage applications. All materials used meet the requirements of the CFR Title 21



Key features

- Highly efficient Mycoplasma retention
- High flow rates and low differential pressure
- Fully validated and integrity testable
- Low extractables

Applications

Due to its chemical compatibility SME-X⁺ P filters are widely used in Pharmaceutical production.

- Retention of particles and micro-organisms in liquids
- Bioburden control and sterilization
- Mycoplasma control in cell culture media

Protecting processes, products and people

Atlas Copco's process filters optimize your productivity while protecting your process, product and consumers. Our portfolio of cartridges and housings covers all your filtration needs. The products are made from proven, high quality materials from reputable suppliers and manufactured in a controlled environment subjected to strict QA/QC procedures.

Technical data

Micron ratings (µm)
0,2/0,1 µm

Cartridge length
10"/20"/30"/40"

Cartridge diameter
69 mm

Effective filtration area (typical)
0.55m2

Material of construction

Filter media:	Double layer Polyethersulfone (PES)
Support Layers:	Polyester
Core:	Polypropylene
Cage:	Polypropylene
End caps:	Nylon, stainless steel reinforcement ring
Seal:	Silicone, EPDM

Maximum operating temperature
80°C (cartridges), 60°C (capsules)

Maximum differential pressure forward (cartridges)
5.0 bar @ 20°C, 1.8 bar @ 82°C

Maximum differential pressure forward (capsules)
5.2 bar @ 38°C, 3.1 bar @ 60°C

Sterilization SIP (cartridges)
≤ 50 cycles @ 121°C for 30 minutes @ dP 0.3 bar

Sterilization Autoclave
100 cycles for 30 mins @ 130°C

Hot water sanitization (cartridges)
50 cycles for 30 minutes @ 85°C

Regulatory compliance

TOC/Conductivity @ 25°C

Autoclaved filter effluent meets USP<643> for total organic carbon and USP<645> for water conductivity per WFI requirements after UPW flush of specified volume

Particle shedding

Autoclaved filter effluent meets USP<788> for large volume injections

Non fiber releasing

Non-fiber releasing component materials meet the criteria for a "non-fiber releasing filter" as per 21 CFR 210.3(b)(6)

Bacterial endotoxin

Aqueous extraction of autoclaved filter contains < 0.25 EU/ml as determined by USP <85> using the Method D (Chromogenic kinetic method)

Bacterial retention to ASTM F838-05 (0,22 µm)
LRV >10^7 CFU/cm^2 of Brevundimonas diminuta (ATCC 19146)

Biosafety

Meets criteria of biological reactivity tests, In Vitro USP <87>

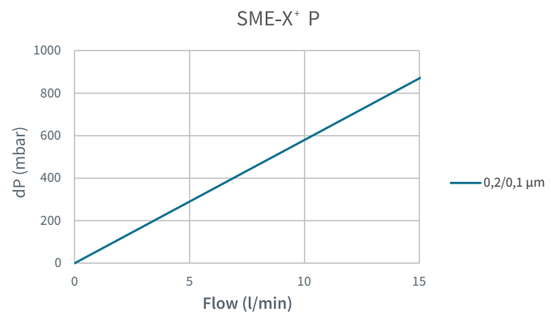
Indirect food additive

The product complies with food contact regulation 21 CFR §177.1500/1520/1630/2440 and (EC) No 1935/2004 incl. subsequent amendments

Quality assurance

For each filter cartridge an electronic Certificate of Conformity is available, detailing relevant test data, biological safety information and product approvals against the specific batch number and part number for the filter. The filter cartridges are manufactured in a controlled clean room environment that generally meets the requirements for ISO 14644-1 Class 7 Cleanrooms.

Flow rate



Note: 10" cartridge tested with water @ 20°C, 1,005 cP (typical flow rate)

Integrity test data

Cartridge	0,2/0,1 µm
Diffusion flow	2.8 bar
10”	< 30 ml/min
Bubblepoint	> 5.5 bar

Product configuration

Series	Rating (µm)	Length	End cap	Seal
SME-X⁺ P	0,2/0,1	10”	C2 (2x226 O-ring + 2 tabs/flat)	E (EPDM)
		20”	C3 (2x222 O-ring/flat)	S (Silicone)
		30”	C7 (2x226 O-ring + 2 tabs/fin)	
		40”	C8 (2x222 O-ring/fin)	
			C28 (2x222 O-ring + 3 tabs/fin)	
			DOE (flat + gasket/flat + gasket)	

Example: SME-X⁺ P 0,2/0,1 µm 30” C7 S

Capsules

Series	Rating (µm)	Length	Connection
SME⁺ P	0,2/0,1	H	0.25” SHB
		S	1.5” TC
		D	
		10”	

Example: SME-X⁺ P 0,2/0,1 µm H 1.5” TC

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