

TECHNICAL DATA SHEET

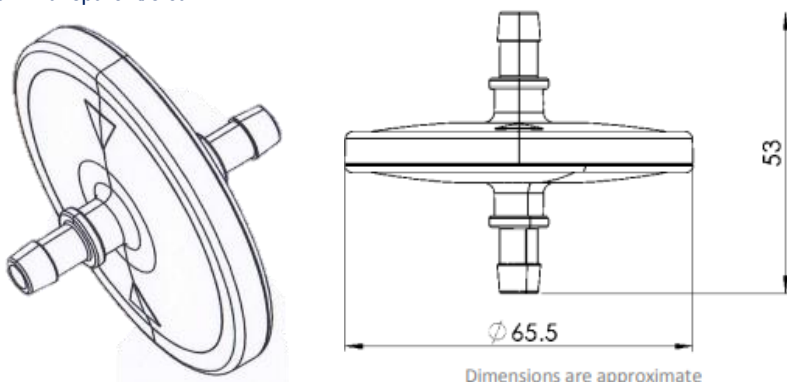
Product code:	M03.1.003
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Description
Suction filter

Application / Intended Use
The hydrophobic suction filter protects surgical suction vacuum pump equipment from contamination.

Classification
Class I - Disposable medical device Annex IX 93/42 / EEC , Annex VIII MDR 2017/745

Product Properties	
Materials	Filter media: 1 µm ePTFE Hydrophobic Membrane Housing Material: Styrene – transparent - Biocompatibility according to ISO 10993-1 - DEHP plasticizer Free and latex free - REACH
Physical/Mechanical	Approx. dimensions: Ø65.5mm x 53mm Weight: Approx. 17g Interfaces (ex: Input / Output connectors): 8mm (approx.) barbed connectors on both sides. Operating temperature Range: N/A Storage temperature Range: 5 °C to 40 °C Flow direction indicated by ▷ ◁ marking on filter face. Colour: Transparent/Clear.  Dimensions are approximate
Viral Filtration Efficiency	Viral Filtration Efficiency in accordance with ASTM F2101-07: Min. 99.9999% (Bacteriophage @ 30L / minute) REP: 863416-S01.1_VFE
Bacterial Filtration Efficiency	Bacterial Filtration Efficiency in accordance with ASTM F2101-07: Min. 99.9999% (Staphylococcus aureus @ 30L /minute) REP: 867672-S01.1_BFE
Effective Filtration Area	24.9cm ²
Water Entry Pressure (media)	16psi
Instructions for Use	Multi-language IFU available.
Product Lifetime	5 years from the date of manufacture. Operating Lifetime: Refer to Instructions for Use.
Cleanliness	Device assembled within Environmentally Controlled Area.
Sterilization	N/A
Applicable Standards	Product Certification required:

	- CE mark Applicable Standards and Technical Regulations: Biological evaluation of Medical Devices - Part 1: Evaluation and Testing - ISO 10993-1 Medical devices- Application of risk management to medical devices - BS EN ISO 14971. Medical devices – symbols to be used with medical device labels, labelling and information to be supplied - Part1: General requirements - ISO 15223-1. High Efficiency Air Filters – BS EN 1822.
Packaging & Labelling	Number of pieces per bag is determined by the sales order. Each bag is labelled with the following traceability information: ❖ Quantity ❖ Product description ❖ Product Date ❖ Lot Number
Alternatives	Different connections and combinations available.
Certificate Of Compliance	CofC available at request based on the lot numbers and date of manufacture. Declaration of Conformity is supplied with each shipment. Medical Filtration Solutions Ltd.'s Quality Management System is in compliance with the requirements of ISO 13485.