MEDICA S.p.A.
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TECHNICAL DATASHEET – 028_DSU-SSU_NS

DEVICE DESCRIPTION

WATER PURIFICATION FILTERS (MEDIAPURE)

MANUFACTURER
MEDICA S.p.A.

INTENDED USE

Thanks to MediSulfone® UF hollow fiber, MediaPure ultrafilters guarantee microbiological purification from bacteria, virus and endotoxins.
All particles above 5 nm are removed from water.

TECHNICAL FEATURES

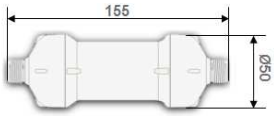
MediaPure DSU

1/2'' thread connection

MediPure SSU28

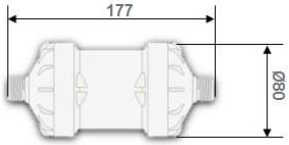
1/2'' thread connection

MediaPure SSU10



3/8'' thread connection

MediaPure SSU14



1/2'' thread connection

	DSU	SSU 10	SSU 14	SSU 28
Internal Membrane Surface (m^2)	2,0 *(stage I)* 1,0 *(stage II)*	0,5	1,4	2,8
Flow at 3 bar (L/min)	9	5	9	19
Expected duration	12 mesi / 10.000 L	12 mesi / 2.000 L	12 mesi / 8.000 L	12 mesi / 15.000 L

Membrane	MediSulfone®
Membrane material	Polysulfone
Potting seal	*Polyurethane*
Cartridge and caps	*ABS (Acrylonitrile Butadiene Styrene)*
Max. inlet pressure	5 bar
Max. inlet temperature	60°C
Cut-off	15.000 Daltons / 5 nm
Bacterial Retention	> 10^{11} (*Brevundimonas diminuta*)
Viral Retention	>10^8 (PhiX-174)
Bacterial Retention	> 10^5 EU/ml

Mediapure sterile filters are assembled and packed without the use of heavy metal, PVC, Plasticizer, BPA, latex and/or animal origin materials.

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PRODUCTION ENVIRONMENT
The Device has been produced in clean room - controlled environments - with restricted contamination, in compliance with the standard ISO 14644 - class 8 (Class 100,000 according to Fed. Std. 209 - E).
INSPECTIONS
The devices are inspected in accordance with Medica Quality System (ISO 9001:2015 and ISO 13485:2016) and biocompatibility test in compliance UNI EN ISO with 10993.
VALIDITY/EXPIRATION DATE
Filter should be installed no later than 5 years after manufacturing date in order to avoid bad ultrafiltration membrane trigger.
PACKAGING
Single packaging: pouch in Tyvek – film hot sealed or paper medical degree and bicoupled film (PA/PE or PP) in compliance with ISO 11607-1. *Small box: each device is positioned inside a small carton box* *Multiple packaging: carton box*
LABELLING
Each package and every single shipping box is provided with a label, including data for the identification of the device and symbols complying with UNI CEI EN ISO 15223-1:2012 Standard. Each single package is provided with a IFU (Instruction for Use) sheet.
STORAGE CONDITIONS AND TRANSPORT
Ensure that the disposable should be preserved from heat, light sources and humidity. Avoid shocks, falls and extreme conditions.
DISPOSAL
The Medical Device, once used, must be eliminated following the DPR 254/2003 (attuation of Art 24 L 179/2002) or following the local disposal law.

CODE	DESCRIPTION
M03500	MEDIAPURE DSU - N° 2 FILETTI 1/2" - NS
M03501	MEDIAPURE SSU 28 - N° 2 FILETTI 1/2" - NS
M03835	MEDIAPURE SSU 10 - N° 2 FILETTI 3/8" - NS
M90016	MEDIAPURE SSU 14 - N° 2 FILETTI 1/2" - NS