Certificate of Conformity

VWR Catalogue Number	514-1263
Description	Sterile Syringe Filters, PES, with 0.22µm Pore Size, 25mm outer Diameter
Lot Number	291071025
Date of Manufacture (yyyy-mm)	2021-06
Date of Sterilzation (yyyy-mm)	2021-07
Expiry Date (yyyy-mm)	2024-07
Country of Origin	Manufactured in China
Date of Issue (yyyy-mm-dd)	2022-01-28

Quality System Compliance

Products are manufactured under the **ISO 9001:2015** standard. Products are inspected and controlled through whole production processing in accordance with current applicable product specifications and QC SOP.

QC Testing

Representative products samples are collected and inspected in accordance with current applicable QC requirements.

Syringe Filter Lot Characterization

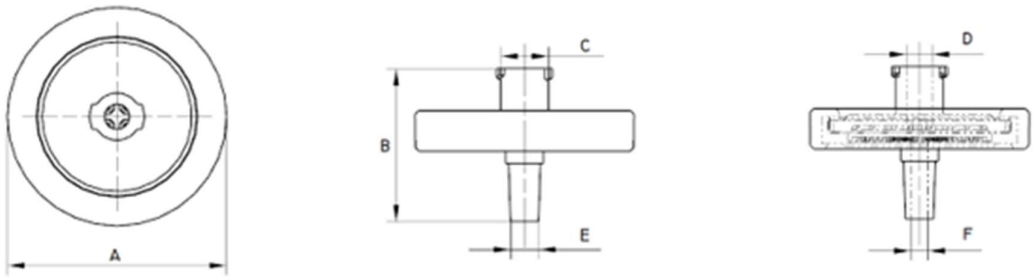
Membrane material	PES	**Filtration area(cm2)**	2.98
Pore size	0.22µm	**Holdup volume (µl)**	<100
Wettability	Hydrophilic	**Housing Material**	Polypropylene
Inlet/Outlet	Female Luer Lock inlet and Male Luer Slip outlet	**Bubble point(psi)**	72.5-81.2
Burst pressure(psi)	87.0	**Flow rate(ml/min@10psi)**	54-59
Bubble point and Flow rate were tested by water at 25 ℃.			

Product Specifications

Material	Housing Material	General purpose polypropylene (PP) Compliance with USP Class VI ; Colour: White
	Membrane Material	PES (polyether sulfone)
Sterilization	Product labelled as sterile is gamma irradiated as per ISO 11137 and meets SAL 10^{-6} with a specified dose range of 20-30kGy.	
ATP Assay	Not Applicable.	
DNase & RNase Free	Not Applicable.	
BSE/TSE	No use of any raw material produced from or substances derived from animal origin. The manufacturing process of the product does not use any ingredient of animal origin and no material derived from or exposed to animals affected by or under quarantine for transmitting Animal Bovine Spongiform Encephalopathy/Spongiform Encephalopathy (BSE)/(TSE).	
Cytotoxicity	Testing is conducted to quality all material resins using ISO 10993 standards for cytotoxicity and have been shown to be non-toxic.	
Non-Pyrogenic Statement	The acceptance level for product is less than 0.25 EU/mL (LAL Gel Clot Method).	
Latex Statement	This product is not made from natural rubber latex.	
BPA Statement	Bisphenols are not used in the manufacture of the raw material and are not expected to be present.	
DEHP Statement	Please see RoHS information below.	
RoHS	No substances (Lead, Cadmium, Mercury, Hexavalent Chromium (Cr6+), Poly Brominated Biphenyls (PBB), Poly Brominated Diphenyl ethers (PBDE), Bis(2-Ethyhexyl) Phthalate (DEHP), Benzyl Butyl Phthalate (BBP), Dibutyl Phthalate (DBP), Diisobutyl Phthalate (DIBP)) are used in manufacturing the raw materials and final product. No routinely analysis is performed.	
REACH Statement	Not Applicable.	
Storage Conditions	Store at normal temperature.	

Annex

Technical Drawing



Detailed List				
Item Number	Item	Diameter 13mm	Diameter 25mm	Diameter 30mm
A	OD of Filter	17.2 ± 0.5	30.0 ± 0.5	34.2 ± 0.5
B	Height of Filter	17.5 ± 0.5	21.0 ± 0.5	23.5 ± 0.5
C	OD Inlet	6.5 ± 0.3	6.5 ± 0.3	6.5 ± 0.3
D	ID Inlet	4.1 ± 0.3	4.1 ± 0.3	4.1 ± 0.3
E	OD Outlet	3.9 ± 0.3	3.9 ± 0.3	3.9 ± 0.3
F	ID Outlet	2.5 ± 0.3	2.5 ± 0.3	2.5 ± 0.3

Choosing the Right Diameter

Typical Process Volume [mL]	Suitable Syringe Filter Diameter [mm]	Hold-up volume[µl]
1-10	Ø13	< 10
10-50	Ø25	< 100
50-100	Ø30	< 120