Certificate of Conformity

VWR Catalogue Number	SF01-38
Description	Syringe Filter, J.T.Baker®, Glass fibre Membrane, 30 mm Diameter, 0.45 µm Pore Size
Lot Number	313059048
Date of Manufacture (yyyy-mm-dd)	2023-05
Country of Origin	Manufactured in China
Date of Issue (yyyy-mm-dd)	2024-08-27

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.

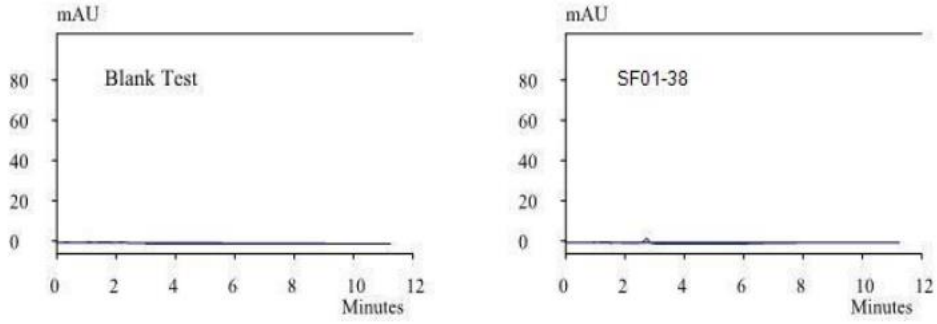
QC Testing

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

Syringe Filter Lot Characterization:

Membrane material	PTFE	**Filtration area(cm2)**	4.9
Pore size	0.45µm	**Holdup volume (µl)**	<120
Wettability	Hydrophilic	**Housing Material**	PP
Inlet/Outlet	Female Luer Lock inlet and Male Luer slip outlet	**Bubble point(psi)**	11.6-17.4
Burst pressure(psi)	87.0	**Flow rate(ml/min@10psi)**	112-156
Bubble point was tested by ethyl alcohol. Flow rate was tested by water at 25℃.			

HPLC Extractable Test(254nm)



Product Specifications

The product is Class I category device as defined by FDA in 21CFR Parts 862-892.

Material	**Housing Material:** PP (General purpose polypropylene, Compliance with USP Class VI; Colour: White). **Membrane Material:** Hydrophilic polytetrafluoroethylene (PTFE). (Compliance with USP Class VI; Colour: White)
Sterilization	Non-Sterile.
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	Not Applicable.
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	Diethylhexyl phthalate (DEHP) is not included in the manufacture or the formulation of the raw materials and are not expected to be present. However, tests have not been performed for these chemical materials.
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.
Shelf Life	4 years.