Certificate of Quality

VWR® VACUUM FILTRATION SYSTEMS, STANDARD LINE

As per the manufacturer, the below product meets the following criteria:

North American Catalog No:	10040-468
Manufacture Lot Number:	200330145
Description:	Filter Upper Cup, 500ml, Pes, 0.2um, St
Date of Manufacture:	March 30, 2020
Date of Sterilization:	April 01, 2020
Expiration Date:	March 30, 2023
Country of Origin:	Made in China

Quality System Compliance

Products are manufactured under the ISO 9001:2015 & ISO13485:2016 standard. Products are Inspected and controlled through whole production processing in accordance with current applicable product specifications and QC SOP. Inspection records are reviewed and signed off by qualified personnel for product release.

QC Testing

Representative production samples are collected and inspected in accordance with current applicable product specifications.

Product Specifications

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

Material: Upper Cup- Polystyrene (PS)
Membrane- Polyether Sulfone (PES)
Hose Connector- Acrylonitrile Butadiene Styrene (ABS)

Maximum Vacuum Pressure: The maximum vacuum pressure of this lot has been validated. The acceptance level for product is not more than -70KPa.

Sterilization Procedure: Product labelled as sterile is EB (Electron Beam) and dose released upon ISO11137 recommended practices in effect at the time of validation. Products labelled sterile meet a minimum requirement of 10^{-6} SAL with a specified dose range of 15-30 kGy.

BSE/TSE Statement: The above product contains no ingredients of animal origin and no material derived from or exposed to animals affected by or under quarantine for Transmitting, Animal Spongiform Encephalopathy (TSE)/Bovine Spongiform Encephalopathy (BSE).

Non-Pyrogenic: The acceptance level for product is 0.5 EU/ml or less than 20 EU/device (TAL Gel Clot Method).

DNase & RNase Free: This product has been tested and is free of any detectable DNase/RNase contamination.

Cytotoxicity: Testing is conducted to qualify all material resins using ISO 10993 standards for cytotoxicity and have been shown to be non-toxic.

Bacterial Retention: According to ASTM F838-05, 100% retentive when challenged with Brevundimonas diminuta (ATCC No.19146) 1×10^{7} cfu/cm2under -70KPa.

Flow Rate: Flow rate of this product has been tested no less than 500mL/min with deionized water under -70KPa.

Latex-Free Statement: The product is Latex free.

BPA Statement: Bisphenol-A (BPA) and Bisphenol-F (BPF) are not used 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.

Heavy metals – RoHS: Raw materials comply with the requirements of the Directive 2002/95/EC, as amended, and 2011/65/Eu concerning the limits of cadmium, lead, mercury, hexavalent chromium, Polybrominated Biphenyls (PBB) and Polybrominated Diphenyl Ethers (PBDE).

DEHP Statement: Not Applicable.

Signed:

Jamie Ethier
VP Global Quality
VWR, Part of Avantor

Date: October 15,2020