Certificate of Conformity

VWR Catalogue Number	See List
Description	VWR®, Bottle-Top Vacuum Filtration Systems, PES
Country of Origin	Manufactured in China
Date of Issue (yyyy-mm-dd)	2025-07-10

Complete Filtration Units

Catalogue Number	Capacity [mL]	Pore Size [µm]	Membrane Diameter [mm]
514-0328	150	0.2	50
514-0329	150	0.45	50
514-0330	250	0.2	50
514-0331	250	0.45	50
514-0332	500	0.2	75
514-0333	500	0.45	75
514-0334	1000	0.2	91
514-0335	1000	0.45	91

Filtration Cups only

Catalogue Number	Capacity [mL]	Pore Size [µm]	Membrane Diameter [mm]
514-0336	150	0.2	50
514-0337	150	0.45	50
514-0338	250	0.2	50
514-0339	250	0.45	50
514-0340	500	0.2	75
514-0341	500	0.45	75
514-0342	1000	0.2	91
514-0343	1000	0.45	91

PS reservoir bottles (caps included)

Catalogue Number	Capacity [mL]
514-0344	150
514-0345	250
514-0346	500
514-0347	1000

Quality System Compliance

This certificate confirms that the product has been sourced from a supplier or manufacturer who has declared their Quality Management System (QMS) complies with **ISO 9001:2015 & ISO 13485:2016.**

QC Testing

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

For Filtration Units and Cups

Bacterial Retention According to ASTM F838-05, 100% retentive when challenged with Brevundimonas diminuta (ATCC No.19146) 1×10^{7}cfu/cm2 under -70KPa.

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

Product Specifications

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

Material Housing: Lid, Cup, Bottle: GPPS (General Polystyrene); Compliance with USP Class VI
Connector: ABS(Acrylonitrile-Butadiene-Styrene);
Hose connector: PP(Polypropylene); Compliance with USP Class VI
Cap: HDPE (High-density of Polyethylene);
Compliance with USP Class VI
Sealing ring: Silicone
Membrane: PES(Polyethersulfone)

Sterilization Product labelled as sterile is EB (Electron beam) irradiated as per ISO 11137 and meets SAL 10^{-6} with a specified dose range of 15-30kGy.

ATP Assay Not Applicable.

Nitrosamine	This product does not contain nitrosamine.
DNase & RNase Free	This product is free of any detectable DNase/RNase contamination.
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) according to EMEA 410/01 revision 3.
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 0.5 EU/mL or less than 20 EU/device (TAL Gel Clot Method). Test passed.
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	Not Applicable.
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	Room temperature.
Shelf Life	3 years.

Disclaimer: VWR's Quality Management System (QMS) is ISO 9001:2015 certified as a wholesale distributor of finished products, ensuring effective oversight of finished product handling, traceability, and distribution processes. VWR is not a manufacture and does not engage in manufacturing, co-manufacturing or processing activities such as design, packaging, labeling, testing or quality release. Consequently, the supplier or manufacturer's QMS certification may differ from VWR's.

VWR states that this declaration will not discharge the user from their obligation to ensure the product is suitable for the intended use. This product is intended for research use only. It is not for use in diagnostic procedures, therapeutic applications, or any human or clinical use.

This document has been produced electronically and is valid without a signature.

Version History

Sl.no	Version number	Description	Month & Year
1	1.0	Created General CoQ using new layout	04-2023
2	1.1	Added USP Class VI information in material	02-2025
3	2.0	Modified Quality system compliance and disclaimer	07-2025