Certificate of Conformity

VWR Catalogue Number	See List
Description	VWR® Roller Bottle
Country of Origin	Manufactured in China
Date of Issue (yyyy-mm-dd)	2025-07-31

Catalogue Number	Description	Capacity [mL]	Growth Area [cm^2]
734-2749	Treated surface, plug-seal cap	1000	490
734-2750	Treated surface, plug-seal cap	2000	850
734-2751	Treated surface, plug-seal cap	2000	850
734-2752	Treated surface, vented cap	2000	850
734-3368	Treated surface, plug-seal cap	2000	850
734-3369	Treated surface, ribbed, plug-seal cap	2000	1900
734-3248	Treated surface, plug-seal cap	5000	1700
734-3249	Treated surface, vented cap	5000	1700
734-3250	Treated surface, plug-seal cap	5000	4250
734-3251	Treated surface, vented cap	5000	4250

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.

Accuracy of Graduations: Graduation accuracy comply with our product specification ±5%.

Product Specifications

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

Material	Bottle- Polystyrene (PS). Cap- High Density Polyethylene (HDPE). Compliance with USP Class VI Growth Surface Type: Treated.
Sterilization	Product labeled as sterile is EB (Electron beam) irradiated and dose released upon ISO11137 recommended practices in effect at the time of validation. Products labeled sterile meets a minimum req uirement of 10^{-6} SAL with a specified dose range of 15–30 kGy.
ATP Assay	Not Applicable.
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 (Cr^{6+}), 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 analyse 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 CoC using new layout	11-2022
2	2.0	Modified Quality system compliance and disclaimer	07-2025