Certificate of Conformity

VWR Catalogue Number	**See List**
Description	**VWR®, Roller Bottles**
Country of Origin	**Manufactured in China**
Date of Issue (yyyy-mm-dd)	**2025-03-24**

Roller bottles, Non-treated

Catalogue Number	Capacity [mL]	Growth Area [cm²]	Packed	Recommended working volume [mL]	Cap Style	Pk
VWRA734-3651	1000	490	1/bag, 24/case	100 - 150	Plug seal cap	24
VWRA734-3652	1000	490	1/bag, 24/case	100 - 150	Vent Cap	24
VWRA734-3653	2000	850	1/bag, 12/case	180 - 260	Plug seal cap	12
VWRA734-3656	2000	1900	1/bag, 12/case	300 - 400	Vent Cap	12
VWRA734-3657	5000	1700	1/bag, 12/case	340 - 510	Plug seal cap	12
VWRA734-3660	5000	4250	1/bag, 12/case	340 - 510	Vent Cap	12

Quality System Compliance

Products are manufactured under the **ISO 9001:2015 & ISO 13485:2016** 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.

Product Specifications

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

Material

Bottle: Polystyrene (PS); Compliance with USP Class VI
Cap: HDPE (High-density of Polyethylene);
Compliance with USP Class VI.
Membrane: 0.22µm hydrophobic PVDF (only use for vent cap).

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.
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	Not Applicable.
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.
RoHS	Raw materials comply with the requirements of the Directive 2011/65/EU as amended and (EU) 2015/863 concerning the limits of cadmium, lead, mercury, hexavalent chromium, Polybrominated Biphenyls (PBB) and Polybrominated Diphenyl Ethers (PBDE), bis(2-ethylhexyl)phthalate (DEHP), butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP) and diisobutyl phthalate(DIBP).
REACH Statement	Not Applicable.
Storage Conditions	Room temperature.
Shelf Life	3 years.

Version History

Sl.no	Version number	Description	Month & Year
1	1.0	Created General CoQ using new layout	03-2025