Certificate of Conformity

VWR Roller Bottle

VWR International certifies that the specified products meet all VWR specifications and quality criteria for release. The products comply in every respect with the relevant particular specifications, drawings, relevant standards and regulations in force.

VWR International certifie que les produits mentionnés respectent toutes les specifications et critères de qualité VWR. Les produits satisfont aux spécifications particulières, aux plans, aux normes et règlements en vigueur s'y rapportant.

VWR International bestätigt hiermit, daß die angegebenen Produkte alle VWR Spezifikationen und Qualitätskriterien zur Freigabe erfüllen. Die Produkte entsprechen in jeder Hinsicht den maßgeblichen Spezifikationen, den Zeichnungen sowie den relevanten Normen und gültigen Vorschriften.

VWR Catalog No: 734-2752

Lot No: 211209679-A

Date of Manufacture: 09th Dec 2021

Expiry Date: 09th Dec 2024

Date of Sterilization: 11th Dec 2021

Description	Capacity (ml)	Growth area (cm^2)	Packed	Pk
Treated surface, vented cap	2000	850	2/bag, 40/case	40

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

Material: Bottle - Polystyrene (PS) Compliance with USP Class VI
Cap – High Density Polyethylene (HDPE) Compliance with USP Class VI

Growth Surface Type: Treated

Cell Growth Area: 850 $cm^{2.}$

ClosureType: Vented Cap (Membrane diamter 50 mm, Thickness 0.1 mm, Pore size 0.22 µm)

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.

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

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

Sterility: Products labeled as sterile is EB (Electron Beam) irradiated and dose released upon ISO11137 recommended practices meets a minimum requirement of 10^{-6} SAL with the 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 of product is 0.5 EU/ml or less than 20 EU/device by TAL Gel Clot Method. Test passed.

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

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

Latex Free statement: Product is Latex Free

BPA Statement: Not applicable.

DEHP Statement: Not Applicable.

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).

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

Date of Issue: **September 2022**