

Certificate of Conformity

VWR Roller Bottle, 1000 ml, Treated Surface, Plug Seal Cap

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 spécifications 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: 734-2749

Lot No: 220415254A

Date of Manufacture: 15th Apr 2022

Expiry Date: 15th Apr 2025

Date of Sterilization: 19th Apr 2022

Description	Capacity (ml)	Growth area (cm ²)	Packed	Pk
Treated Surface, Plug seal cap	1000	490	2/bag, 40/case	40

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.

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

Certificate of Conformity

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

Material: Bottle - Polystyrene (PS), Compliance with USP Class VI.
Cap - Polyethylene (PE), Compliance with USP Class VI.

Sterility: Product labelled as sterile is EB (Electron beam) irradiated and dose released upon ISO11137 recommended practices in effect at the time of validation. Products labelled sterile meets 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) according to EMEA 410/01 rev. 3.

Non-pyrogenic: The acceptance level of product is 0.5 EU/ml or less than 20 EU/device by 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 quality all material resins using ISO 10993 standards for cytotoxicity and have been shown to be non-toxic.

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).

Latex Free: Product is Latex free

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

Date of Issue: **May 2022**