# Certificate of Conformity

# VWR Roller Bottle, 5000 ml, Plug Seal Cap, Treated surface

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:** 734-3248

**Lot No:** 191217597

**Date of Manufacture:** 17th Dec 2019

**Expiry Date:** 17th Dec 2022

**Date of Sterilization:** 18th Dec 2019

**Material:** Bottle - Polystyrene (PS)
Cap – High Density Polyethylene (HDPE)

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

**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. 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.

**Growth Surface Type:** Treated

**Cell Growth Area:** 1700 $cm^2$

**Closure Style:** Plug Seal Cap

# Certificate of Conformity

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

**Sterilization Procedure:** Product labeled as sterile is gamma irradiated and dose released upon ISO11137 recommended practices in effect at the time of validation. Products labeled sterile meets a minimum requirement of $10^{-6}$ SAL with a specified dose range of 12 – 24 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).

**BPA Statement:** Not Applicable.

**DEHP Statement:** Not Applicable.

**Non-Pyrogenic:** The acceptance level for product is 0.5 EU/ml or less than 20 EU/device. (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.

**Latex free statement:** The product is Latex free.

**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 Polibrominated Diphenyl Ethers (PBDE).

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

Date of Issue: **February 2021**