

Certificate of Conformity

VWR Reagent Reservoir, PS

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 Cat.No.: 613-1171

Lot number: 181314

Date of Manufacture: 14th Aug 2018

Date of Sterilization: 21st Aug 2018

Sterilization Expiry Date: 21st Aug 2023

Capacity	Type	Sterility level	Packed	Pk
100 ml	PS	Sterile	5/bag, 40 bags/case	200

Quality System Compliance: Products are manufactured under the ISO 9001:2015 and ANSI/AAMI ISO 11137 standard as well as internal SOP.

QC Testing: Representative production samples are inspected according to level S4 AQL 0.4 sampling plan per ANSI/ASQ Z1.4-2008 standard.

Accuracy: ≤ 95 %

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

Sterilization Process: Product have undergone electron beam irradiation according to ANSI/AAMI standards under ISO 11137-2 guidelines, and are certified Pre-sterile with a sterility assurance level of 10^{-3} (minimum dosage: 4.0 kGy, maximum dosage: 26.4 kGy)

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BPA statement: BPA Free

Phthalate/ DEHP Statement: Phthalates are not added to products as plasticizers. However, traces of phthalates may be present in some products as impurities from catalytic system.

RoHS compliance: This product complies with the requirements of the Directives 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).

BSE/TSE Statement: These products do not contain, nor were they produced from any animal products.

Non-Pyrogenic: Endotoxin level is < 0.06 EU/ ml.

DNase/RNase Free: No DNase and RNase activity detected.

Cytotoxicity: Not applicable

Nucleic acids: No amplicons detected

Latex Free Statement: This product is latex free.

ATP Statement: Detection level <7⁻⁹ mg/μl

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

Date of issue: **November 2020**