

# Certificate of Conformity

|                                   |                                                          |
|-----------------------------------|----------------------------------------------------------|
| <b>VWR Catalogue Number</b>       | 613-1171                                                 |
| <b>Description</b>                | <b>Reagent Reservoirs</b> , 100 mL, Polystyrene, Sterile |
| <b>Lot Number</b>                 | 1008702395                                               |
| <b>Expiry Date (yyyy-mm-dd)</b>   | 2028-09                                                  |
| <b>Country of Origin</b>          | Manufactured in Mexico                                   |
| <b>Date of Issue (yyyy-mm-dd)</b> | 2023-12-08                                               |

## Quality System Compliance

Products are manufactured under the **ISO 9001:2015 and ANSI/AAMI ISO 11137** standards. 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. Inspected according to level S4 AQL 0.4 sampling plan per ANSI/ASQ Z1.4-2008 standard.

**PCR Inhibitor:** Products are tested via PCR amplification and gel electrophoresis analysis.

## Product Specifications

|                               |                                                                                                                                                                                                                              |
|-------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Material</b>               | Polystyrene.                                                                                                                                                                                                                 |
| <b>Sterilization</b>          | Product labelled as sterile are irradiated and dose released upon ISO 11137-2:2013 recommended practices in effect at the time of validation meet a minimum requirement of $10^{-3}$ SAL.                                    |
| <b>ATP Assay</b>              | Products are tested via luminescence detection (detection limit $2.5 \times 10^{-10}$ mg/ $\mu$ L) for the presence of ATP and the assay resulted with a value of $2.5 \times 10^{-10}$ to $7.2 \times 10^{-9}$ mg/ $\mu$ L. |
| <b>DNase &amp; RNase Free</b> | This product is free of any detectable DNase/RNase contamination. Test sensitivity is $10^{-7}$ Kunitz units/ $\mu$ L.                                                                                                       |
| <b>DNA Statement</b>          | Product is DNA free.                                                                                                                                                                                                         |

|                                |                                                                                                                                                                                                                                                                                                                                                                      |
|--------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>BSE/TSE</b>                 | 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).          |
| <b>Cytotoxicity</b>            | This product is free of cytotoxicity effects.                                                                                                                                                                                                                                                                                                                        |
| <b>Non-Pyrogenic Statement</b> | The acceptance level for product is 0.06 EU/mL (LAL Gel Clot Method).                                                                                                                                                                                                                                                                                                |
| <b>Latex Statement</b>         | This product is not made from natural rubber latex.                                                                                                                                                                                                                                                                                                                  |
| <b>BPA Statement</b>           | This product is free of Bisphenol A.                                                                                                                                                                                                                                                                                                                                 |
| <b>DEHP Statement</b>          | Please see RoHS information below.                                                                                                                                                                                                                                                                                                                                   |
| <b>RoHS</b>                    | No substances (Lead, Cadmium, Mercury, Hexavalent Chromium (Cr6+), Poly Brominated Biphenyls (PBB), Poly Brominated Diphenyl ethers (PBDE), Bis(2-Ethyhexyl) Phthalate (DEHP), Benzyl Butyl Phthalate (BBP), Dibutyl Phthalate (DBP), Diisobutyl Phthalate (DIBP)) are used in manufacturing the raw materials and final product. No routinely analyse is performed. |
| <b>REACH Statement</b>         | No substances as listed on >Substance of Very High Concern< candidate list published 2023-06-14 are used in manufacturing of the raw materials used to produce this product. No routinely analysis is performed.                                                                                                                                                     |
| <b>Storage Conditions</b>      | Store in a Room temperature.                                                                                                                                                                                                                                                                                                                                         |

Disclaimer: VWR states that this declaration will not discharge the user from their obligation to ensure the product is suitable for the intended use. The purpose of the product is for use in laboratory only.  
This document has been produced electronically and is valid without a signature.