

Certificate of Conformity

VWR Catalogue Number	129-0011
Description	Twist-Seal Bags, Closure with 1 round and 1 flat wire, without write-on panel, 4000 mL, with 101 µm thickness and 254×305 mm dimension, Sterile
Lot Number	J094439
Expiry Date (yyyy-mm)	2027-01
Country of Origin	Manufactured in Canada
Date of Issue (yyyy-mm-dd)	2022-09-20

Quality System Compliance

Products are manufactured under the **ISO 9001:2015** standard. 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.

Product Specifications

Material Low Density Polyethylene (LDPE).

Product should not be used at temperatures greater than 80 °C (176 °F), or temperature less than 100 °C (-148 °F) tolerances: ± 10% on mil. thickness, ± 1/8" on width and ± 1/4" length.

These bags comply to the applicable regulations of the Food and Drug Administration (21 CFR 177.1520 (c)3.1a, (c)3.2a and 178.2010) and to the European Union No 10/2011 regulation.

Sterilization Sterility by manufacturing is ensured by extrusion temperatures exceeding 220 °C which eliminates any present bacteria. Only once the bag is opened by tearing along the perforated line in the bag's interior susceptible to possible contamination from its present environment. Periodic validation tests, based on USP 40 - Sterility testing, are performed to guaranty the sterility. Products have been validated to have SAL 10⁻³

ATP Assay	Not applicable.
DNase & RNase Free	This product is free of any detectable DNase/RNase contamination.
BSE/TSE	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).
Cytotoxicity	Not applicable.
Non-Pyrogenic Statement	Products are free from pyrogen.
Latex Statement	This product is not made from natural rubber latex.
BPA Statement	Bisphenol are not used in the manufacture of the raw material and are not expected to be present.
DEHP Statement	Please see RoHS information below.
RoHS	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.
REACH Statement	No substances as listed on >Substance of Very High Concern< candidate list published 2022-06-10 are used in manufacturing of the raw materials used to produce this product. No routinely analysis is performed.
Storage Conditions	Recommended general storage of the product is at ambient temperature and protect from any possible contamination.

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.
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