

Certificate of Conformity

VWR Catalogue Number	See List
Description	Twist-Seal Bags, Sterile
Country of Origin	Manufactured in Canada
Date of Issue (yyyy-mm-dd)	2023-08-11

Closure with 2 round wires, without write-on panel

Catalogue Number	Capacity [ml]	Thickness [µm]	Dimension [mm]
129-9021	60	63	76×127
129-9022	130	63	76×178
129-9813	355	63	114×190
129-9814	450	63	114×229
129-9809	800	63	114×305
129-9810	1200	63	114×382
129-9816	650	63	140×229
129-9815	1500	63	140×382

Closure with 2 round wires, with write-on panel

Catalogue Number	Capacity [ml]	Thickness [µm]	Dimension [mm]
129-9023	60	63	76×127
129-9884	130	63	76×178
129-9885	450	63	114×229
129-9817	800	63	114×305
129-9886	650	76	140×229
129-9847	1650	76	178×305
129-9887	1650	76	178×305

Closure with 1 round and 1 flat wire, without write-on panel

Catalogue Number	Capacity [ml]	Thickness [μm]	Dimension [mm]
129-9019	130	63	76×178
129-9803	450	63	114×229
129-9801	800	63	114×305
129-9802	1200	63	114×382
129-9805	650	76	140×229
129-0417	1080	76	140×305
129-9804	1500	76	140×382
129-0418	1650	76	178×305
129-0010	2250	101	254×305
129-0011	4000	101	254×305

Closure with 1 round and 1 flat wire, with write-on panel

Catalogue Number	Capacity [ml]	Thickness [μm]	Dimension [mm]
129-9020	130	63	76×178
129-9807	450	63	114×229
129-9806	800	63	114×305
129-9808	650	76	140×229
129-9856	1650	76	178×305
129-9863	1650	76	178×305
300-0107	1650	76	178×305
129-0012	2250	101	254×305
129-0013	4000	101	254×382

Jumbo type, strong, with 2 flat wires, without write-on panel

Catalogue Number	Capacity [ml]	Thickness [μm]	Dimension [mm]
129-9024	3000	101	305×305
129-9025	4250	101	305×356
129-9026	5500	101	305×406
129-9027	6750	101	305×457
129-9028	8000	101	305×508

Catalogue Number	Capacity [ml]	Thickness [μ m]	Dimension [mm]
129-1161	10500	101	305×610
129-1162	13000	101	305×711
129-9800	15000	101	382×610

Opaque bag: closure with 2 round wires, with write-on panel

Catalogue Number	Capacity [ml]	Thickness [μ m]	Dimension [mm]
129-9870	450	63	114×229

Closure with 2 round wires, with write-on panel, Bags with regular tabs

Catalogue Number	Capacity [ml]	Thickness [μ m]	Dimension [mm]
129-9029	1650	76	178×305

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: $\pm 10\%$ on mil. thickness, $\pm 1/8$ " on width and $\pm 1/4$ " 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.
Extractable and leachable	There is no leachable/extractable according to FDA and EU 10/2011 regulations.
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 2021-07-08 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.
Shelf Life	5 Years.

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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