

# Certificate of Conformity

<b>VWR Catalogue Number</b>	See List
<b>Description</b>	Double Pouch, Twist-Seal Bags for Cleanroom Application, Sterile
<b>Country of Origin</b>	Manufactured in Canada
<b>Date of Issue (yyyy-mm-dd)</b>	2022-02-23

Safety Tabs – Clear - Closure with 2 round wires

Catalogue Number	Capacity [ml]	Thickness [µm]	Dimension [mm]
129-9889	800	63	114 × 305
129-9000	650	76	140 × 229
129-9001	1500	76	140 × 382
129-9002	1650	76	178 × 305

Safety Tabs – Printed - Closure with 2 round wires

Catalogue Number	Capacity [ml]	Thickness [µm]	Dimension [mm]
129-9003	800	63	114 × 305
129-9004	650	76	140 × 229
129-9005	1500	76	140 × 382
129-9006	1650	76	178 × 305

Safety Tabs – Clear - Closure with 1 round wire and 1 flat wire

Catalogue Number	Capacity [ml]	Thickness [µm]	Dimension [mm]
129-9007	650	63	140 × 229
129-9008	650	101	140 × 229
129-9890	1080	76	140 × 305
129-9009	1650	76	178 × 305
129-9010	1650	101	178 × 305

Catalogue Number	Capacity [ml]	Thickness [µm]	Dimension [mm]
129-9011	2250	101	254 × 305
129-0665	4000	101	254 × 382

Safety Tabs – Printed - Closure with 1 round wire and 1 flat wire

Catalogue Number	Capacity [ml]	Thickness [µm]	Dimension [mm]
129-9012	650	76	140 × 229
129-9013	650	101	140 × 229
129-9014	1080	76	140 × 305
129-9015	1650	76	178 × 305
129-9016	1650	101	178 × 305
129-9017	2250	101	254 × 305
129-9018	4000	101	254 × 382

## Quality System Compliance

Products are manufactured under the **ISO 9001:2015 & NF ISO 14644-1, ISO 14698, ISO 14644** 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).

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** Products are gamma irradiated. Sterilisation procedure is validated in conformity with ISO 11137-1 and ISO 11137-2 to guarantee SAL 10<sup>-3</sup>.

Periodic validation tests, based on USP 40 - Sterility testing, are performed to guaranty the sterility.

<b>ATP Assay</b>	Not applicable.
<b>DNase &amp; RNase Free</b>	This product is free of any detectable DNase/RNase contamination.
<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>	Not applicable.
<b>Non-Pyrogenic Statement</b>	Products are free from pyrogen.
<b>Latex Statement</b>	This product is not made from natural rubber latex.
<b>BPA Statement</b>	Bisphenol are not used in the manufacture of the raw material and are not expected to be present.
<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 analysis is performed.
<b>REACH Statement</b>	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.
<b>Storage Conditions</b>	Recommended general storage of the product is at ambient temperature and protect from any possible contamination.
<b>Shelf Life</b>	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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