

Thermo Fisher Scientific hereby certifies that the product identified below is manufactured and/or distributed according to the requirements of product and quality specifications as maintained in our quality management system which is compliant to ISO 13485:2016 (BSI Certificate Number: FM 653694) in the USA.



Alan E. Hatch  
 Sr. Quality Manager

The following information represents Product Certification for: Item#: **141744**

Description: **R Btl,1450CM<sup>2</sup>, PS,Easy On/Off Vent DB,ST** Lot#: **1373140**

Use Before: **10/24/2027**

Manufactured: **10/23/2022**

Part Number	Description	Common Name	DMF#	Cytotoxicity	USP Class VI	FDA Compliance - 21 CFR
1-0649-62P	BTL,ROLLER,STD/WT,PLEATED,PS,I SBM,JOBFIT	COMPONENT PART				
8-0077-50	RESIN,PS,ISBM	POLYSTYRENE, NATURAL, ISBM	23986	PASSED	PASSED	177.1640, 176.170
1-0649-23	ROLLER BOTTLE CAP INJ MLD JOB FIT WHITE	COMPONENT PART				
8-0043-02P	RESIN,HDPE,INJ,12450,WHITE	COMPONENT PART				
8-0043-00	RESIN,HDPE,INJ, DOW 12450N	HIGH DENSITY POLYETHYLENE	N/A	PASSED	PASSED	177.1520(c)3.2a use conditions A-H
8-0097-50	RESIN,COLORANT,WHITE	COLORANT, WHITE	N/A	PASSED	PASSED	177.1520, 178.2010,178.3297 use conditions A-H

If N/A appears in any of the columns above it means the information is not available. Any item listed as "COMPONENT PART" will show blank in the DMF#, Cytotoxicity, USP Class VI, and FDA Compliance Information columns.

If the word "PASSED" appears in the USP Class VI column next to the resin listing, this material has passed USP Class VI requirements, latest Volume, as part of our initial test approval protocol.

If the word "PASSED" appears in the Cytotoxicity column next to the resin listing, this material was tested and shown to be non-cytotoxic as part of our initial test approval protocol, using either mouse fibroblast L929 cells or the more sensitive human diploid lung cell lines WI-38 or MRC-5.

Product was Gamma Irradiation Sterilized. Product was dosimetric released per ANSI/AAMI/ISO 11137 guidelines. Product meets the minimum requirement of 10<sup>-3</sup> SAL (Sterility Assurance Level). Product was determined to be non-pyrogenic at a level < 0.1 EU/ml per USP < 85 > .

This tissue culture treated product has representative samples subjected to an actual performance test for growth with L929 cells. Cells are plated to be confluent within 72 hours. A minimum of 90% confluency is required for lot acceptance.