

Thermo Fisher Scientific hereby certifies that the product identified below is manufactured according to the requirements of product and quality specifications as maintained in our quality management system which is compliant to ISO 13485 (BSI Certificate Number: FM 653694) or ISO 9001 (BSI Certificate Number: FM 743358) in Monterrey, NL, MEX.



 Ruben Deschamps
 Sr. Quality Manager
 05/31/2025

 The following information represents Product Certification for: Item#: **DS2408-0500**

 Description: **WSHBTLM WM RED UNTRY LDPE;500ML**

 Lot#: **1429359**

 Manufactured: **05/16/2025**

Part Number	Description	Common Name	DMF#	Cytotoxicity	USP Class VI	FDA Compliance - 21 CFR
1-1220-81P	WASH/BTL,500ML,UNTRY,LDPE,RED	COMPONENT PART				
8-0049-43P	RESIN,LDPE,RED,IBM,EBM	COLOR MIX (LDPE, RED)	N/A	N/A	N/A	N/A
8-0049-31	RESIN,LDPE,IBM,EBM,EXT	LOW-DENSITY POLYETHYLENE	1572	PASSED	PASSED	176.170(c), 177.1520(c)2.2,use conditions B-H
8-0099-75	COLOR,RED,MULTI	COLORANT, RED (MULTI-RESIN)	N/A	PASSED	PASSED	177.1350, 1520, 1580, 1620,178.2010, 3297, 181.28,184.1210 use conditions B-H
1-1220-85	SPOUT,WASH/BTL,250ML,UNTRY,RED	COMPONENT PART				
8-0049-21P	RESIN,LLDPE,RED,NOT FDA	COLOR MIX (LDPE, RED, NOT FDA)	N/A	N/A	N/A	N/A
8-0049-06	RESIN,LLDPE,INJ	LLDPE, INJECTION	N/A	N/A	N/A	177.1520 (c) 3.1a
8-0099-98	COLOR,RED,LLDPE,NOT FDA	COLORANT, RED, NOT FDA	N/A	N/A	N/A	Not FDA
1-1813-46	CLOS,38/415,PP,RED,NALGE	COMPONENT PART				

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.