

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 13485:2016 (BSI Certificate Number: FM 653694) in Monterrey Mexico.



Ana Martinez  
 Quality Manager

The following information represents Product Certification for: Item#: **595-4520**

Certificate issued: **04/12/2019**

Description: **BTLTOP,A-PES,45MM,500ML,75MM**

Lot#: **1253822**

Use Before: **04/28/2024**

Manufactured: **04/05/2019**

Part Number	Description	Common Name	DMF#	Cytotoxicity	USP Class VI	FDA Compliance - 21 CFR
1-0014-44	COV,FLT,500mL,THERMO	COMPONENT PART				
8-0077-12	RESIN,PS,INJ,IBM	POLYSTYRENE	1623	PASSED	PASSED	177.1640
1-0014-90	UPPER,FLT,500 ML, MF-75, PS	COMPONENT PART				
8-0077-12	RESIN,PS,INJ,IBM	POLYSTYRENE	1623	PASSED	PASSED	177.1640
1-0014-95	ADP,FLT,Q/D,LDPE,WHT,MF-75	COMPONENT PART				
8-0049-14P	RESIN,LDPE,WHT,INJ	COLOR MIX (LDPE, WHT, INJ)	N/A	N/A	N/A	N/A
8-0049-01	RESIN,LDPE,INJ	LOW-DENSITY POLYETHYLENE	9522	PASSED	PASSED	177.1520(a)(2)(i)
8-0099-26	COLOR,WHT,OLF	COLORANT, WHITE	N/A	N/A	N/A	178.3297, 170.39, use C-G, notfor articles used for holdingfood during cooking
1-0014-86	COLLAR,FLT,45/75,MF75,HIPS,BLU	COMPONENT PART				
8-0077-18P	RESIN,PS,HIGH IMPACT,BLU,INJ	COLOR MIX	N/A	PASSED	PASSED	N/A
8-0077-13	RESIN,PS,HIGH IMPACT,INJ	POLYSTYRENE	1623	PASSED	PASSED	177.1640
8-0099-74	COLOR,BLUE,MULTI	COLORANT, BLUE, MULTI-RESIN	N/A	PASSED	PASSED	177.1350, 1520, 1580, 1620,178.2010, 3297, 181.28,184.1210

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 was determined to be non-pyrogenic at a level < 0.25 EU/ml per USP < 85 > .