

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 (BSI Certificate Number: FM 653694) or ISO 9001 (BSI Certificate Number: FM 743358) in Rochester, NY, USA.



Alan E. Hatch
 Sr. Quality Manager
 01/20/2025

The following information represents Product Certification for: Item#: **DS0320-2545**

Description: **BTL,FLT,REUSBL,PSF,250ML,45MM**

Lot#: **7444985010**

Manufactured: **10/10/2024**

Part Number	Description	Common Name	DMF#	Cytotoxicity	USP Class VI	FDA Compliance - 21 CFR
8-0053-14P	Blend, PSF and release additive	COMPONENT PART				
8-0053-13	Polysulfone release additive	COMPONENT PART				
8-0053-01	RESIN,PSF,INJ	POLYSULFONE	MAF 31	PASSED	PASSED	177.1655, repeated use,conditions A-H, single usecondition H
1-0070-53	CAP,VAC,REUSEABLE FLT	COMPONENT PART				
8-0005-30	Resin,TPE,FDA,INJ	RESIN,TPE,FDA,INJ	10824	PASSED	PASSED	177.1810(b)(3), 177.1210 and 177.2600
8-0053-14P	Blend, PSF and release additive	COMPONENT PART				
8-0053-13	Polysulfone release additive	COMPONENT PART				
8-0053-01	RESIN,PSF,INJ	POLYSULFONE	MAF 31	PASSED	PASSED	177.1655, repeated use,conditions A-H, single usecondition H
8-0053-14P	Blend, PSF and release additive	COMPONENT PART				
8-0053-13	Polysulfone release additive	COMPONENT PART				
8-0053-01	RESIN,PSF,INJ	POLYSULFONE	MAF 31	PASSED	PASSED	177.1655, repeated use,conditions A-H, single usecondition H
1-0070-53	CAP,VAC,REUSEABLE FLT	COMPONENT PART				
8-0005-30	Resin,TPE,FDA,INJ	RESIN,TPE,FDA,INJ	10824	PASSED	PASSED	177.1810(b)(3), 177.1210 and 177.2600
8-0053-14P	Blend, PSF and release additive	COMPONENT PART				
8-0053-13	Polysulfone release additive	COMPONENT PART				
8-0053-01	RESIN,PSF,INJ	POLYSULFONE	MAF 31	PASSED	PASSED	177.1655, repeated use,conditions A-H, single usecondition H
1-0070-83	RING,LOCKING,REUSEABLE,FLT H	COMPONENT PART				
8-0053-12P	RESIN,PSF,WHITE,INJ	COMPONENT PART				

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Part Number	Description	Common Name	DMF#	Cytotoxicity	USP Class VI	FDA Compliance - 21 CFR
8-0053-01	RESIN,PSF,INJ	POLYSULFONE	MAF 31	PASSED	PASSED	177.1655, repeated use,conditions A-H, single usecondition H
8-0099-49	COLOR,WHT,PSF	COLORANT, WHITE	N/A	N/A	N/A	177.3297;170.39, repeated use,condition A-H, single use H (not rec. for medical devices)
8-0053-13	Polysulfone release additive	COMPONENT PART				
1-0070-79	ADP,TBG,REUSABLE FLT	COMPONENT PART				
8-0070-50P	RESIN,PP,GRANITE,INJ	COMPONENT PART				
8-0071-06	Resin,PP,Inj	POLYPROPYLENE, INJECTION	9988	PASSED	PASSED	177.1520(a)(1)(i), (c)1.1a,177.1520(b), (use conditionsA-H)
8-0099-30	COLOR,GRANITE	COLORANT, GRANITE	N/A	N/A	N/A	177.1350, 1520, 1580, 1620,178.2010, 3297, 181.28,184.1210
8-0053-14P	Blend, PSF and release additive	COMPONENT PART				
8-0053-13	Polysulfone release additive	COMPONENT PART				
8-0053-01	RESIN,PSF,INJ	POLYSULFONE	MAF 31	PASSED	PASSED	177.1655, repeated use,conditions A-H, single usecondition H
8-0053-14P	Blend, PSF and release additive	COMPONENT PART				
8-0053-13	Polysulfone release additive	COMPONENT PART				
8-0053-01	RESIN,PSF,INJ	POLYSULFONE	MAF 31	PASSED	PASSED	177.1655, repeated use,conditions A-H, single usecondition H

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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.