

Thermo Fisher Scientific hereby certifies that the product identified below is produced, inspected and found to be in compliance with product and quality specification requirements as documented in our ISO 13485:2003 Quality Management System (QMI-SAI Global File No. 1606319 and 1606321) in the USA.



Janet Cosgrove
 Raw Materials and
 Product Compliance Manager

The following information represents Product Certification for: Item#: **300-4050**

Certificate issued: **11/21/2016**

Description: **FILTRHOLDR W/RCVR PSF;500 ML**

Lot#: **7250140010**

Manufactured: **07/11/2016**

Part Number	Description	Common Name	DMF#	Cytotoxicity	USP Class VI	FDA Compliance - 21 CFR
1-0070-42	COV,REUSABLE FLT,500ML	COMPONENT PART				
8-0053-02	RESIN,PSF,RELEASE,INJ	POLYSULFONE (RELEASE, INJ)	MAF 31	PASSED	PASSED	177.1655, repeated use,conditions A-H, single usecondition H
1-0070-44P	LOWER,CNTNR,REUSABLE FLT,500ML	COMPONENT PART				
8-0053-02	RESIN,PSF,RELEASE,INJ	POLYSULFONE (RELEASE, INJ)	MAF 31	PASSED	PASSED	177.1655, repeated use,conditions A-H, single usecondition H
1-0070-45	MIDSECTION,REUSBL FLT,500/1000	COMPONENT PART				
8-0053-02	RESIN,PSF,RELEASE,INJ	POLYSULFONE (RELEASE, INJ)	MAF 31	PASSED	PASSED	177.1655, repeated use,conditions A-H, single usecondition H
1-0070-48P	UPPER,CNTNR,REUSABLE FLT,500ML	COMPONENT PART				
8-0053-02	RESIN,PSF,RELEASE,INJ	POLYSULFONE (RELEASE, INJ)	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				
8-0053-02	RESIN,PSF,RELEASE,INJ	POLYSULFONE (RELEASE, INJ)	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)
1-0070-53	CAP,VAC,REUSEABLE FLT	COMPONENT PART				
8-0005-24	RESIN,TPE,FDA,INJ	THERMOPLASTIC ELASTOMER	1180	PASSED	PASSED	177.1810(b)(2), FCN679,177.1210, 177.2600
1-0070-75P	SPRT,DISC,REUSABLE FLT	COMPONENT PART				

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Part Number	Description	Common Name	DMF#	Cytotoxicity	USP Class VI	FDA Compliance - 21 CFR
8-0053-12P	RESIN,PSF,WHITE,INJ	COMPONENT PART				
8-0053-02	RESIN,PSF,RELEASE,INJ	POLYSULFONE (RELEASE, INJ)	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)
1-0070-76P	BODY,SPRT PLT,REUSABLE FLT HOL	COMPONENT PART				
8-0053-12P	RESIN,PSF,WHITE,INJ	COMPONENT PART				
8-0053-02	RESIN,PSF,RELEASE,INJ	POLYSULFONE (RELEASE, INJ)	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)
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
1-0070-82	SPRT,PLT,1 PC,REUSABLE FLT	COMPONENT PART				
8-0053-02	RESIN,PSF,RELEASE,INJ	POLYSULFONE (RELEASE, INJ)	MAF 31	PASSED	PASSED	177.1655, repeated use,conditions A-H, single usecondition H
1-0070-90	CAP,STOR,REUSABLE FLT	COMPONENT PART				

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Part Number	Description	Common Name	DMF#	Cytotoxicity	USP Class VI	FDA Compliance - 21 CFR
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)

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.