

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  
 10/15/2025

The following information represents Product Certification for: Item#: **300-4000**

Description: **FILTRHOLDER W/RCVR PSF;250ML**

Lot#: **7461831010**

Manufactured: **09/03/2025**

| Part Number | Description                     | Common Name       | DMF#   | Cytotoxicity | USP Class VI | FDA Compliance - 21 CFR                                                                  |
|-------------|---------------------------------|-------------------|--------|--------------|--------------|------------------------------------------------------------------------------------------|
| 1-0070-53   | CAP,VAC,REUSEABLE FLT, TPE      | 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    |        |              |              |                                                                                          |
| 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    |        |              |              |                                                                                          |
| 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                             |
| 1-0070-75P  | SPRT,DISC,REUSABLE FLT          | 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           |        |              |              |                                                                                          |
| 1-0070-76P  | BODY,SPRT PLT,REUSABLE FLT HOL  | COMPONENT PART           |        |              |              |                                                                                          |
| 8-0053-12P  | RESIN,PSF,WHITE,INJ             | COMPONENT PART           |        |              |              |                                                                                          |
| 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           |        |              |              |                                                                                          |

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Manufactured: **09/03/2025**

| 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 |
| 8-0053-14P  | 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 |
| 1-0070-90   | CAP,STOR,REUSABLE FLT           | 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)  |

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.