

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 13485:2016 (BSI Certificate Number: FM 653694) in the USA.

 Alan E. Hatch
 Sr. Quality Manager

The following information represents Product Certification for: Item#: **DS0315-0047**

Description: **FUNNEL,FLT/CLMP,PSF;47MM,250ML**

Lot#: **1348417**

Manufactured: **03/03/2022**

| Part Number | Description | Common Name | DMF# | Cytotoxicity | USP Class VI | FDA Compliance - 21 CFR |
|-------------|----------------------------|----------------------------|--------|--------------|--------------|--|
| 1-0062-98P | FUN, GLA FLT FUN, 47MM | COMPONENT PART | | | | |
| 8-0053-02 | RESIN, PSF, RELEASE, INJ | POLYSULFONE (RELEASE, INJ) | MAF 31 | PASSED | PASSED | 177.1655, repeated use, conditions A-H, single use condition H |
| 1-0062-99P | DISC, SUPPORT, GLA FLT FUN | COMPONENT PART | | | | |
| 8-0053-02 | RESIN, PSF, RELEASE, INJ | POLYSULFONE (RELEASE, INJ) | MAF 31 | PASSED | PASSED | 177.1655, repeated use, conditions A-H, single use condition H |
| 1-0070-75 | SPRT, DISC, GLA FLT HOLDER | 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 use condition 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) |
| 1-0062-96 | COV, FLT FUN, GLA, 47MM | COMPONENT PART | | | | |
| 8-0028-12P | RESIN, PPCO, BLK, INJ | COMPONENT PART | | | | |
| 8-0028-04 | RESIN, PPCO, RAD STER, INJ | POLYPROPYLENE COPOLYMER | 7478 | PASSED | PASSED | 177.1520 (a)(3)(i) & (c)3.1(a) except for cooking, (use conditions C-H) |
| 8-0099-43 | COLOR, BLK, MULTI | COLORANT, BLACK | N/A | N/A | N/A | 177.1350, 1520, 1560, 2600, 178.3297, 181.28 |
| 1-0062-97P | UPPER, GLA FLT FUN, 47MM | COMPONENT PART | | | | |
| 8-0053-02 | RESIN, PSF, RELEASE, INJ | POLYSULFONE (RELEASE, INJ) | MAF 31 | PASSED | PASSED | 177.1655, repeated use, conditions A-H, single use condition 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 |

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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.