

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*

Alan E. Hatch  
Sr. Quality Manager  
12/09/2024

The following information represents Product Certification for: Item#: **2630-0050**

Description: **3 IN SANITARY CARBOY, 50L;PP**

Lot#: **7437861010**

Manufactured: **06/03/2024**

Part Number	Description	Common Name	DMF#	Cytotoxicity	USP Class VI	FDA Compliance - 21 CFR
1-1452-98P	CRBY,50L,RND,SR,PPHO,W/HDLS	COMPONENT PART				
8-0071-07	RESIN,PP,IBM,EBM,EXT	POLYPROPYLENE	9988	PASSED	PASSED	177.1520(a)(3)(i), (c)3.2a,(use conditions A-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.

Carboy Height is verified to be 25.4" +/- 0.4".  
Ferrule inner diameter is verified to be 2.86" +/- 0.040".

DMF # and cytotoxicity information are not available for the PP ferrule.

The resins used for the carboy and ferrule meet all FDA compliance identified under CFR 177.1520 (c) 1.1a for contact with food and drugs except what is listed under Type IV-A and Type V.

ANIMAL DERIVED MATERIALS (BSE/TSE) - All resins and colorants used at the manufacturing site comply with the latest revision of EMA/410/01 section 6.4. The purchased component(s) used in this product also comply with the latest revision of EMA/410/01 section 6.4.