

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
 05/30/2025

The following information represents Product Certification for: Item#: **165305**

Description: **96OBP POLYMER BLACK CC W/LID**

Lot#: **1429755**

Manufactured: **05/23/2025**

Part Number	Description	Common Name	DMF#	Cytotoxicity	USP Class VI	FDA Compliance - 21 CFR
009302F02P	96OBP POLYMER BOTTM NUNC BLACK	COMPONENT PART				
14213MRP	RESIN,BLEND,BLACK,PS,CHROMA	COMPONENT PART				
8-0077-05	RESIN,POLYSTYRENE	PS, NATURAL, BASE RESIN	18492	N/A	PASSED	177.1640
14174MR	CONCENTRATE,BLACK,CHROMA	COLORANT, BLACK, INJ.	N/A	N/A	N/A	Not FDA
009326B00	LID,S/S PLATE,NUNC,PS,CLR	COMPONENT PART				
14149MR	RESIN,POLYSTYRENE	NATURAL, POLYSTYRENE, INJ.	18492	PASSED	PASSED	177.1640

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.

Product was Gamma Irradiation Sterilized. Product was dosimetric released per ANSI/AAMI/ISO 11137 guidelines. Product was determined to be non-pyrogenic at a level < 0.5 EU/ml per USP < 85 > .