

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.



Tresa O'Shea
Manager, Regulatory Compliance

The following information represents Product Certification for: Item#: **2640-0130**

Certificate issued: **02/24/2015**

Description: **CRBY W/SANITARY FLANGE PP;50L**

Lot#: **1141671**

Manufactured: **02/09/2015**

Part Number	Description	Common Name	DMF#	Cytotoxicity	USP Class VI	FDA Compliance - 21 CFR
1-1452-99P	CRBY, 50L, RND, 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)
1-1820-29	CLOS, 83B, PP, WHT, NALGE	COMPONENT PART				
8-0071-11P	RESIN, PP, WHI, INJ	POLYPROPYLENE, WHITE, INJ.	N/A	PASSED	PASSED	N/A
8-0071-06	Resin, PP, Inj	POLYPROPYLENE, INJECTION	9988	PASSED	PASSED	177.1520(a)(1)(i), (c)1.1a, 177.1520(b), (use conditions A-H)
8-0099-34	COLOR, WHT, MULTI	COLORANT, WHITE	16513	PASSED	PASSED	177.1350, 1520, 1620, 178.3297, 181.28
1-1822-97	RING, SEAL, 83B, TPE	COMPONENT PART				
8-0005-24	RESIN, TPE, FDA, INJ	THERMOPLASTIC ELASTOMER	1180	PASSED	PASSED	177.1810(b)(2), FCN679, 177.1210, 177.2600

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.

The ferrule attached to the carboy is manufactured from polypropylene (PP). The DMF# of the PP is #1698. The material complies with USP Class VI requirements and is FDA compliant with 21 CFR 177.1520.