

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
 07/12/2025

The following information represents Product Certification for: Item#: **2319-0050**

Description: **CRBY AUTOCL W/SPGT PP;20L**

Lot#: **1432357**

Manufactured: **07/07/2025**

Part Number	Description	Common Name	DMF#	Cytotoxicity	USP Class VI	FDA Compliance - 21 CFR
1-1456-97P	CRBY, 20L, RND, PP, W/SPGT	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				
8-0005-30	Resin, TPE, FDA, INJ	RESIN, TPE, FDA, INJ	10824	PASSED	PASSED	177.1810(b)(3), 177.1210 and 177.2600
1-3725-87	Q/D, FEMALE, SIZE A, HDPE, ANON	COMPONENT PART				
8-0042-01	RESIN, HDPE, INJ	HIGH-DENSITY POLYETHYLENE	1646	PASSED	PASSED	176.170(c), 177.1520(c)3.2a
1-4320-97	CAP, VALVE STEM	COMPONENT PART				
8-0071-12P	RESIN, PP, BLUE, 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 conditions A-H)
8-0099-74	COLOR, BLUE, MULTI	COLORANT, BLUE, MULTI-RESIN	N/A	PASSED	PASSED	177.1350, 1520, 1580, 1620, 178.2010, 3297, 181.28, 184.1210
1-4321-98P	VALVE, STEM, PP, Q/A SPGT	COMPONENT PART				
8-0071-12P	RESIN, PP, BLUE, INJ	COMPONENT PART				

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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)
8-0099-74	COLOR,BLUE,MULTI	COLORANT, BLUE, MULTI-RESIN	N/A	PASSED	PASSED	177.1350, 1520, 1580, 1620,178.2010, 3297, 181.28,184.1210
1-4321-94P	BODY,PP,Q/A,SPGT,ANON	COMPONENT PART				
8-0071-12P	RESIN,PP,BLUE,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)
8-0099-74	COLOR,BLUE,MULTI	COLORANT, BLUE, MULTI-RESIN	N/A	PASSED	PASSED	177.1350, 1520, 1580, 1620,178.2010, 3297, 181.28,184.1210
1-4321-95P	NUT,LOCK,PP,WHT,SPGT,NEW	COMPONENT PART				
8-0029-18P	RESIN,PPCO,WHT,INJ	COLOR MIX (PPCO, WHT, RESIN)	N/A	N/A	N/A	N/A
8-0029-04	RESIN,PP,COPOLYMER,INJ	POLYPROPYLENE COPOLYMER	1698	N/A	N/A	177.1520(a)(3)(i) and(c)3.1a, 3.2a
8-0099-34	COLOR,WHT,MULTI	COLORANT, WHITE	16513	PASSED	PASSED	177.1350, 1520, 1620,178.3297, 181.28
1-4321-95P	NUT,LOCK,PP,WHT,SPGT,NEW	COMPONENT PART				
8-0029-18P	RESIN,PPCO,WHT,INJ	COLOR MIX (PPCO, WHT, RESIN)	N/A	N/A	N/A	N/A
8-0029-04	RESIN,PP,COPOLYMER,INJ	POLYPROPYLENE COPOLYMER	1698	N/A	N/A	177.1520(a)(3)(i) and(c)3.1a, 3.2a
8-0099-34	COLOR,WHT,MULTI	COLORANT, WHITE	16513	PASSED	PASSED	177.1350, 1520, 1620,178.3297, 181.28
1-4321-96	PLUG,TPE,SPGT CLOS	COMPONENT PART				

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Part Number	Description	Common Name	DMF#	Cytotoxicity	USP Class VI	FDA Compliance - 21 CFR
8-0005-03	RESIN, TPE, INJ	THERMOPLASTIC ELASTOMER	N/A	N/A	N/A	177.1210 used in contact with non-fatty foods as a closure/sealing gasket, 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.

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.