

Tel 585-586-8800 75 Panorama Creek Drive, Rochester, NY 14625 Product Certificate Thermo Scientific Nalgene and Nunc Products

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Alan E. Hatch Sr. Quality Manager 07/02/2025

06/16/2025

Manufactured:

The following information represents Product Certification for: Item#: 5045-0003

Thermo Fisher Scientific hereby certifies that the product identified below is manufactured and/or

management system which is compliant to ISO 13485 (BSI Certificate Number: FM 653694)

distributed according to the requirements of product and quality specifications as maintained in our quality

Description: CRYOGNC CLSR COLOR CD PS; BLU Lot#: 1431063

or ISO 9001 (BSI Certificate Number: FM 743358) in Rochester, NY, USA.

Part Number	Description	Common Name	DMF#	Cytotoxicity	USP Class VI	FDA Compliance - 21 CFR
1-3825-77P	CLOS,COLOR CODER,PS,BLU,CRYOVL	COMPONENT PART				
8-0077-24P	RESIN, PS, BLU, HIGH IMPACT, INJ	COLOR MIX	N/A	N/A	N/A	N/A
8-0077-13	RESIN, PS, HIGH IMPACT, INJ	POLYSTYRENE	1623	PASSED	PASSED	177.1640
8-0099-60	COLOR, BLU, PS	COLORANT, BLUE	N/A	N/A	N/A	177.1640, 178.2010, 3297

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.