

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

Manufactured:

Thermo Scientific Nalgene and Nunc Products

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 06/17/2025

04/03/2025

The following information represents Product Certification for: Item#: **2242-0025** 

Description: FLUORO JERRICA; 2.5 GAL 10L Lot#: 7454398010

Part Number	Description	Common Name	DMF#	Cytotoxicity	USP Class VI	FDA Compliance - 21 CFR
1-0610-11	JERRICAN,10L,HDPE,R/F FLUOR	COMPONENT PART				
1-1441-97	STRAP,53B CLOS,JERRICAN	COMPONENT PART				
8-0042-01	RESIN,HDPE,INJ	HIGH-DENSITY POLYETHYLENE	1646	PASSED	PASSED	176.170(c), 177.1520(c)3.2a
1-1821-31P	CLOS,53B J-CAN,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 conditionsA-H)
8-0099-34	COLOR,WHT,MULTI	COLORANT, WHITE	16513	PASSED	PASSED	177.1350, 1520, 1620,178.3297, 181.28
8-0042-31	RESIN,HDPE,IBM,EBM,EXT	HIGH-DENSITY POLYETHYLENE	3310	PASSED	PASSED	177.1520 (c) 3.2a

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 inside and outside surfaces of these bottles/closures have been exposed to fluorine gas under controlled temperature and pressure conditions.

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.