ThermoFisher SCIENTIFIC

Tel 585-586-8800 Fax 585-899-7605
75 Panorama Creek Drive, Rochester, NY 14625

Product Certificate

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 13485:2016 (BSI Certificate Number: FM 653694) in the USA.

June Gulisano
Sr. Quality Manager

The following information represents Product Certification for: Item#: **6422-0010**

Certificate issued: **11/12/2020**

Description: **SPIGOT QUICK ACTION PP**

Lot#: **1301391**

Manufactured: **10/28/2020**

Part Number	Description	Common Name	DMF#	Cytotoxicity	USP Class VI	FDA Compliance - 21 CFR
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 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
1-4321-98P	VALVE,STEM,PP,Q/A SPGT	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
1-4321-94P	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

ThermoFisher SCIENTIFIC

Tel 585-586-8800 Fax 585-899-7605
75 Panorama Creek Drive, Rochester, NY 14625

Product Certificate

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 13485:2016 (BSI Certificate Number: FM 653694) in the USA.

June Gulisano
Sr. Quality Manager

The following information represents Product Certification for: Item#: **6422-0010**

Certificate issued: **11/12/2020**

Description: **SPIGOT QUICK ACTION PP**

Lot#: **1301391**

Manufactured: **10/28/2020**

Part Number	Description	Common Name	DMF#	Cytotoxicity	USP Class VI	FDA Compliance - 21 CFR
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

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.