


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.

 Janet Cosgrove
 Raw Materials and
 Product Compliance Manager

The following information represents Product Certification for: Item#: **1-0500-92**

Certificate issued: **09/13/2016**

Description: **CLOS, 63MM, BLUE PP / BLUE TPE**

Lot#: **1182981**

Manufactured: **08/03/2016**

Part Number	Description	Common Name	DMF#	Cytotoxicity	USP Class VI	FDA Compliance - 21 CFR
8-0005-17P	RESIN,TPE,KB CLOS - BLUE	BLUE TPE BLEND	N/A	N/A	N/A	N/A
8-0005-24	RESIN,TPE,FDA,INJ	THERMOPLASTIC ELASTOMER	1180	PASSED	PASSED	177.1810(b)(2), FCN679,177.1210, 177.2600
8-0098-47	COLOR,TPE,KB CLOS - BLUE	BLUE TPE COLORANT	N/A	N/A	N/A	177.1520, 178.2010, 3297, 3860
8-0028-01P	RESIN,PPCO,KB CLOS - BLUE	BLUE PPCO BLEND	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
8-0098-46	COLOR,PPCO,KB CLOS - BLUE	BLUE PPCO COLORANT	N/A	N/A	N/A	177.1520, 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.