

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



11/29/2022

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.

An E Hahl Alan E. Hatch Sr. Quality Manager

Manufactured:

The following information represents Product Certification for: Item#: 362820-0112

Description: CLOS, MPV YELLOW CODER, PPCO; 11MM Lot#: 1375951

Part Number Description Common Name DMF# Cytotoxicity USP Class VI FDA Compliance - 21 CFR CLOS, PPCO, PACKAGING VIAL COMPONENT PART 1-3828-83 PASSED PASSED 8-0028-04 RESIN, PPCO, RAD STER, INJ POLYPROPYLENE COPOLYMER 7478 177.1520 (a)(3)(i) & (c)3.1(a)except for cooking, (useconditions C-H) 1-3828-95 COLOR CODER, YEL, PKG VIAL COMPONENT PART 8-0077-11P RESIN, PS, HIGH IMPACT, YEL, INJ HIGH IMPACT PS, YELLOW N/A PASSED PASSED N/A RESIN, PS, HIGH IMPACT, INJ PASSED 177.1640 8-0077-13 POLYSTYRENE 1623 PASSED COLOR. YEL 8-0099-32 COLORANT, YELLOW N/A PASSED PASSED 177.1350, 1520, 1580, 1620,178.2010, 3297, 181.28,184.1210 use conditions B-H

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.