

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* June Gulisano  
Sr. Quality Manager

The following information represents Product Certification for: Item#: **2016-0125**

Certificate issued: **04/29/2019**

Description: **BOTTLE SQUARE PPCO; 125ML**

Lot#: **1254310**

Manufactured: **04/12/2019**

Part Number	Description	Common Name	DMF#	Cytotoxicity	USP Class VI	FDA Compliance - 21 CFR
1-0636-92P	BTL,125ML,SQ,N/M,PP	COMPONENT PART				
8-0028-03	RESIN,PPCO,IBM,EBM	POLYPROPYLENE COPOLYMER	6345	PASSED	PASSED	177.1520 (a)(3)(i) & (c)3.2(a)(use conditions A-H)
1-1811-07	CLOS,38/430,PP,NAT,NALGE	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)

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.

Resin was tested and is in compliance with European Pharmacopoeia monograph 3.1.6 as stated by the resin manufacturer.