



June Gulisano Thermo Fisher Scientific hereby certifies that the product identified below is manufactured and/or distributed Den Delisono according to the requirements of product and quality specifications as maintained in our quality management Sr. Quality Manager system which is compliant to ISO 13485:2016 (BSI Certificate Number: FM 653694) in the USA.

The following information represents Product Certification for: Item#: 362015-0500

Description: BTL,SQ PC 500ML,TRAY W/O CL

Lot#: 1295915

Certificate issued: 11/02/2020

Manufactured: 10/23/2020

Part Number	Description	Common Name	DMF#	Cytotoxicity	USP Class VI	FDA Compliance - 21 CFR
1-0639-98P	BTL,500ML,SQ,N/M,PC	COMPONENT PART				
8-0056-01	RESIN, PC, INJ, IBM	POLYCARBONATE	1562	PASSED	PASSED	177.1580

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.