

## PRODUCT CERTIFICATE

September 26, 2018

The following information represents Product Certification for:

Catalog Number: <u>376813</u> Lot Number: <u>1193321</u>

Description: 200mL Conical Tube PP w/Cap

Date of Manufacture: 01/24/2017
Shelf Life None assigned

Thermo Fisher Scientific hereby certifies that the product identified below is inspected and released according to the requirements of product and quality specifications as maintained in our quality management system which is compliant to ISO 13485:2003 (BSI Certificate Number: FM 653694).

Product sterility is assured to an SAL of 10-6 through bioburden control, dose auditing and irradiation according to ANSI/AAMI/ISO 11137 guidelines.

The PPCO resin used to manufacture the tube has passed USP Class VI requirements, latest Volume, as part of our initial test approval protocol. The material was also tested and shown to be non-cytotoxic as part of initial test approval protocol, using either mouse fibroblast L929 cells or the more sensitive human diploid lung cell lines WI-38 or MRC-5.

Sincerely,

Tammy Parmelee
Tammy Parmelee

Tammy Parmelee
Quality Systems Administrator
Thermo Fisher Scientific
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