ThermoFisher SCIENTIFIC

No. 297 Taishan Road Suzhou,
PRC China 215129

+86 512 6737 4588 Tel
+86 512 6737 4589 Fax

Thermo Scientific
Product Certificate

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 13485:2016 Quality Management System in Suzhou, China.

Certificate issued: **02/22/2024**

Alice Chen

Alice Chen
Inspector Leader

The following information represents Product Certification for Item: **374511**
Description: **2.0mL Int Uncoded WP Grads UniLatch Rack**

Lot: 60774930

Manufactured: **12/09/2023**
Use Before: **12/28/2025**

Part Number	Description	Common Name	DMF #	Cytotoxicity	USP Class VI	USA FDA Compliance - 21 CFR
1-3830-87	TUBE,INT THD,2.0ML,PPCO, WIP	COMPONENT PAR				
8-00-28-04	RESIN,PPCO,RAD STER,IN	POLYPROPYLENE COPOLYME	7478	PASSED	PASSED	177.1520 (a)(3)(i) & (c)3.1(a)except for cooking, (use conditions C-H)
1-0025-73	CAP,CRYOVIAL 2/5mL NON-PIERCEABLE	COMPONENT PAR				
8-0028-04	RESIN,PPCO,RAD STER,IN	POLYPROPYLENE COPOLYME	7478	PASSED	PASSED	177.1520 (a)(3)(i) & (c)3.1(a)except for cooking, (use conditions C-H)
8-0005-22	RESIN,TPV,NAT,45 DURO SANTOPRENE	THERMOPLASTIC RUBBE	12719	PASSED	PASSED	N/A

If N/A appears in any of the columns above it means the information is not available. Any item listed as "COMPONENT PART" will be 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 <88> Biological Reactivity Tests, In vivo, Class VI requirements, current edition, 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.

The closure was manufactured at Thermo Fisher Scientific, Rochester, NY, USA. The compliance information for the resin and colorant used to produce this component is included in the above table.

Product was electron-beam (e-beam) radiation sterilized. Product was dosimetric released per ANSI/AAMI/ISO 11137 guidelines. Product was determined to be non-pyrogenic at a level < 0.5 EU/ml per USP < 85 >.
Product is certified to be free of detectable RNase/DNase contamination. This test is performed using the nuclease assay method with a detection limit of 8 x 10^ -7 Kunitz unit/ul for DNase and 1.9 x 10^ -10 Kunitz unit/ul for RNase.)