

Thermo Fisher Scientific hereby certifies that the product identified below is manufactured 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 Monterrey Mexico.



Ana Martinez
 Quality Manager

The following information represents Product Certification for: Item#: **145-0045**

Description: **ANAL TEST FNL CN;0.45MC**

Lot#: **1372128**

Use Before: **10/02/2024**

Manufactured: **10/03/2022**

Part Number	Description	Common Name	DMF#	Cytotoxicity	USP Class VI	FDA Compliance - 21 CFR
1-0014-40	COV,FLT,115mL,THERMO	COMPONENT PART				
8-0077-12	RESIN,PS,INJ,IBM	POLYSTYRENE	1623	PASSED	PASSED	177.1640
1-0035-97	EXTENDER,EC FILTER,PP	COMPONENT PART				
8-0028-04	RESIN,PPCO,RAD STER,INJ	POLYPROPYLENE COPOLYMER	7478	PASSED	PASSED	177.1520 (a)(3)(i) & (c)3.1(a)except for cooking, (useconditions C-H)
1-0037-89	SPRT,FUN,EC ANL FLT,BLU	COMPONENT PART				
8-0077-24P	RESIN,PS,BLU,HIGH IMPACT,INJ	COLOR MIX	N/A	N/A	N/A	N/A
8-0077-13	RESIN,PS,HIGH IMPACT,INJ	POLYSTYRENE	1623	PASSED	PASSED	177.1640
8-0099-60	COLOR,BLU,PS	COLORANT, BLUE	N/A	N/A	N/A	177.1640, 178.2010, 3297
1-0037-98	UPPER, EC ANL FLT,100ML	COMPONENT PART				
8-0029-02	RESIN,PPCO,CLARIFIED,INJ	PPCO, CLARIFIED, INJ	6677	PASSED	PASSED	177.1520 and 176.170

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.

Product has been ETO Sterilized. Product was released per ANSI/AAMI/ISO 11135 guidelines.