

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#: **5100-0001**

Description: **CONTRL RATE FREZER;1.2/2.0ML**

Lot#: **7398124010**

Manufactured: **06/09/2022**

Part Number	Description	Common Name	DMF#	Cytotoxicity	USP Class VI	FDA Compliance - 21 CFR
1-0660-94	JAR,500ML,STR/S,PC	COMPONENT PART				
8-0056-53	RESIN,PC,INJ	POLYCARBONATE, INJ./IBM	N/A	PASSED	PASSED	177.1580
1-1804-15	CLOS,120/415,HDPE,BLUW/O SLR	COMPONENT PART				
8-0042-18P	RESIN,HDPE,BLU,INJ	COLOR MIX (RESIN, HDPE, BLUE)	N/A	PASSED	PASSED	N/A
8-0042-01	RESIN,HDPE,INJ	HIGH-DENSITY POLYETHYLENE	1646	PASSED	PASSED	176.170(c), 177.1520(c)3.2a
8-0099-74	COLOR,BLUE,MULTI	COLORANT, BLUE, MULTI-RESIN	N/A	PASSED	PASSED	177.1350, 1520, 1580, 1620,178.2010, 3297, 181.28,184.1210
1-3608-95	INSR,1.2&2.0ML,HDPE,GRANITE	COMPONENT PART				
8-0042-10P	RESIN, HDPE, GRANITE, INJ	COMPONENT PART				
8-0042-01	RESIN,HDPE,INJ	HIGH-DENSITY POLYETHYLENE	1646	PASSED	PASSED	176.170(c), 177.1520(c)3.2a
8-0099-30	COLOR,GRANITE	COLORANT, GRANITE	N/A	N/A	N/A	177.1350, 1520, 1580, 1620,178.2010, 3297, 181.28,184.1210

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.

ANIMAL DERIVED MATERIALS (BSE/TSE) - All resins and colorants used at the manufacturing site comply with the latest revision of EMA/410/01 section 6.4. The purchased component(s) used in this product also comply with the latest revision of EMA/410/01 section 6.4.