

Am Kalkberg 37520 Osterode am Harz

Product Certification

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Senior Manager Quality

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 13485:2016 and 21 CFR 820 in Germany.

The following information represents Product Certification for: Item#: **75003872**

Certificate issued: **Jun/24/2019**

Description: 2000 ml BIOS Bottle (set of 2) Lot #: **1795**

Part Number	Description	Common Name	DMF#	Cytotoxicity	USP Class VI	USP 661.1	FDA Compliance – 21 CFR
50153003	2000 ml BIOS Bottle	Component Part	-	Passed	Passed	-	-
-	Resin used for Bottle	Polypropylene	014881	Passed	-	Passed	177.1520 (a)(3)(i), (b) and (c) 3.1a, 176.170(c) (use conditions B-H)
50154728	2000 ml BIOS Bottle closure	Component Part	-	Passed	Passed	-	-
-	Resin used for closure	Polypropylene	031608	Passed	Passed	-	177.1520 (a)(3)(i) & (c)(1), (b) and (c) 3.1a, 176.170(c) (use conditions C-G)

Any item listed as "COMPONENT PART" will show blank in the DMF# column.

If the word "PASSED" appears in the USP Class VI column next to the component part listing, this material was tested per USP 41 <88> and passed USP Class VI requirements as part of the initial validation protocol.

If the word "PASSED" appears in the Cytotoxicity column next to the component part listing, this material was tested per USP 41 <87> and shown to be non-cytotoxic as part of the initial validation approval protocol.