

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 13485:2003 Quality



Robert Prescott Mgr. QA/RA

11/24/2010

The following information represents Product Certification for: Item#: 312089-0002

Management System (QMI-SAI Global File No. 1606319 and 1606321) in the USA.

Certificate issued: 12/10/2010

Manufactured:

Description: BTL PACKAGING HDPE; 60MLNM= = Lot#: 1034817

Part Number Description Common Name DMF# Cytotoxicity USP Class VI FDA Compliance - 21 CFR BTL,60ML,RND,N/M,HDPE,PKG COMPONENT PART 1-0423-91P PASSED PASSED 8-0042-31 RESIN, HDPE, IBM, EBM, EXT HIGH-DENSITY POLYETHYLENE 3310 177.1520 (c) 3.2a 1-1811-22 CLOS,20/415,PP,NAT,ANON COMPONENT PART 8-0071-06 Resin, PP, Inj POLYPROPYLENE, INJECTION 9988 PASSED PASSED 177.1520(a)(1)(i), (c)1.1a(use conditions A-H)

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.