

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



Tresa O'Shea
Manager, Regulatory Compliance

The following information represents Product Certification for: Item#: **131866**

Certificate issued: **12/11/2014**

Description: **Pre-Assemb.CF10, Lonza, Sterile**

Lot#: **1136046**

Manufactured: **11/13/2014**

Part Number	Description	Common Name	DMF#	Cytotoxicity	USP Class VI	FDA Compliance - 21 CFR
1-0025-82P	Cell Factory Plate, 2-cavity	COMPONENT PART				
14149MR	RESIN,POLYSTYRENE	NATURAL, POLYSTYRENE, INJ.	18492	PASSED	PASSED	177.1640

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 was Gamma Irradiation Sterilized between 25-40 kGy to a 10⁻⁶ SAL. 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 > .

The port, plug and cap materials have been tested and shown to comply with USP Class VI requirements and have been shown to be non-cytotoxic.

This product has been validated in accordance with the following tests:
 Monolayer Formation: Two different cell lines and a primary cell culture.
 Cloning Efficiency: Specially selected cell line with high sensitivity to toxic components.