

Certificate of Compliance

Description: 3L Expansion Bag Catalog #: 91-200-86
Lot #: 705079
Expiration Date: JAN 2023
Irradiation Date: FEB 2021
Storage -20 to 40°C Country of Manufacture: USA

Notes:

This is to certify that this product has been manufactured in a manner compliant with current Good Manufacturing Practices (cGMPs), FDA regulation 21 CFR part 820 and ISO 13485 Quality Standard.

The fluid pathways are classified USP Class VI and/or ISO-10993. The fluid path raw materials conform to the European guidance EMA/410/01 and the U.S. CFR Title 9 of Part 94.18

For research and manufacturing uses. Not for human therapeutic use.

Physical Inspection: Each manufacturing lot is sampled and tested in accordance with Standard Operating Procedures.

Visual Attributes: Visual examination of the product.

Packaging: Inspection for packaging integrity, accurate labeling and correct product configuration.

Sterilization: The product has been irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 Sterilization of healthcare products - Requirements for validation and routine control - Radiation sterilization. Sterility Assurance Level: SAL 10^-6

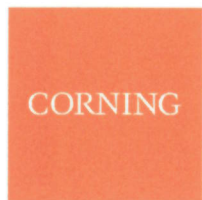
Endotoxin: The fluid path of representative finished product has been sampled and tested according to current USP <85> Bacterial Endotoxins test by LAL passes the FDA acceptance criteria of <=0.5 EU/mL.

For further information, contact Corning Scientific Support at 800-492-1110 or ScientificSupport@corning.com

Following signatures indicate the above material has met all quality specifications and has been reviewed by a Quality representative.

Written By/Date: [Signature] 13 Mar 2021

Reviewed By/Date: [Signature] 17 Mar 2021



Mediatech, Inc.
A Corning Subsidiary
9345 Discovery Boulevard
Manassas, VA 20109
1-800-492-1110
www.corning.com