

Certificate of Compliance

Description:	3L Expansion Bag	Catalog #:	91-200-86
		Lot #:	702729
		Expiration Date:	2022/05
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. This product has been inspected and tested in accordance with currently approved Mediatech, Inc. applicable material specification and drawing requirements.

The fluid pathways are classified USP 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. Utilization of this product apart from the labeled intended use may be a violation of local and/or Federal Law.

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

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: Theresa Taylor 14 JUL 2020

Reviewed By/Date: Benji 14 JUL 2020

SOP Q 04.032 Rev 2



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