

Certificate of Compliance

Description:	3L Expansion Bag	Catalog #:	91-200-86
		Lot #:	705125
		Expiration Date:	FEB 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. 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 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: Olivia Taylor 13 mar 2021

Reviewed By/Date: James Peters / 4E 17 Mar 2021



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