

Certificate of Compliance

Description: 3L Expansion Bag	Catalog #:	91-200-86
	Lot #:	705123
	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.

Biological Reactivity: All product contact materials have passed USP Class VI testing (USP <88>) and/or ISO10993.

Irradiation Dose: 27.3 KGY to 36.8 KGY

Endotoxin: Samples of finished containers were tested for the presence of endotoxin (per the USP Bacterial Endotoxins Test). Aqueous extracts contained ≤ 20 EU/device as determined by the Limulus Amebocyte Lysate Test (LAL).

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: Deirdre Taylor 16 Nov 2021

Reviewed By/Date: Racquel Ferrero / QE
16 Nov 2021



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