Mediatech, Inc.
A Corning Subsidiary

Certificate of Compliance

Description:	3L Expansion Bag	**Catalog #:**	91-200-86
		Lot #:	711032
		Expiration Date:	09-2024
		Irradiation Date:	09-2022
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.

Biological Reactivity: All product contact materials have passed USP Class VI testing (USP <88>) and / or ISO 10993.

Gamma Irradiation: Fully assembled Cryogenic Containers are gamma irradiated. Dosimeter measurement confirms all portions of the packing environment received 25-40 kGy. The minimum dose of 25 kGy has been validated as the SAL 10^{-6} dose in accordance with ANSI/AAMI/ISO 11137-2: Method VDmax25.

Endotoxin: Samples of finished containers were tested for the presence of endotoxin (per the USP Bacterial Endotoxin 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: Elisabeth Walter 17DEC2022 Reviewed By/Date: 19DEC2022

CORNING

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