Mediatech, Inc.
A Corning Subsidiary

Certificate of Compliance

Description:	**5 Liter Bag**	**Catalog #:**	91-200-05
		Lot #:	9954G-0000
		Expiration Date:	NOV/2024
Storage	**10 to 34°C**	**Irradiation Date:**	DEC/2021
		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 use and further manufacturing use only; Not for use in diagnostic or therapeutic procedures. Utilization of this product apart from the labeled intended use may be a violation of local and/or Federal Law.

Test	Specification	Units	Results
Irradiation Dose	**25.0 – 45.0**	**kGy**	**Pass**

Inspection: This Lot of Container Systems has been 100% visually inspected per specification.

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

Cytotoxicity: All product contact films have passed cytotoxicity testing (USP <87> MEM Elution).

Physiochemical: All product contact films have passed USP Physiochemical Tests for Plastics (USP<661).

EP Testing: All product contact films have passed EP<3.2.2.1> "Plastic Containers for Aqueous Solutions for Parental Infusion".

Endotoxin: Samples of representative Lot are routinely tested in periodic validations for the presence of endotoxin per the USP Bacterial Endotoxin Test (USP <85>). Aqueous extracts contained <0.25 EU/ml as determined by the Limulus Amebocyte Lysate Test (LAL).

Particulate: Samples of representative Lot have been routinely tested in periodic validations and have passed requirements per Particulate Matter in Injections Light Obscuration Particulate Count Test (USP<788>).

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 27JAN2022 Reviewed By/Date: George 28 JAN 2022

CORNING

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