

## Certificate of Compliance

<b>Description:</b> 5 Liter Bag	<b>Catalog #:</b>	91-200-05
	<b>Lot #:</b>	993B7-0000
	<b>Expiration Date:</b>	JUL 2024
	<b>Irradiation Date:</b>	JUL 2021
<b>Storage</b> 10 to 34°C	<b>Country of Manufacture:</b>	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 use and further manufacturing use only. Not for use in diagnostic or therapeutic procedures.

**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:** 28.1 KGY to 39.0 KGY

**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  $\leq 0.5$  EU/mL.

For further information, contact Corning Scientific Support at 800-492-1110 or [ScientificSupport@corning.com](mailto: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: *Julia A Taylor* 09 Aug 2021

Reviewed By/Date: *Patricia Peters* / 15  
10 Aug 2021



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