

## Certificate of Compliance

<b>Description:</b>	<b>20 Liter Rocker Bag</b>	<b>Catalog #:</b>	91-200-78
		<b>Lot #:</b>	98W39-0000
		<b>Expiration Date:</b>	2023/12
<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 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.

**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<sup>-6</sup>

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: Olivia Taylor 13 Jan 2021

Reviewed By/Date: George 15 JAN 2021



Mediatech, Inc.  
A Corning Subsidiary  
9345 Discovery Boulevard  
Manassas, VA 20109  
1-800-492-1110  
[www.corning.com](http://www.corning.com)