

## Certificate of Compliance

**Description:** 22 L Rocker Bag

**Storage:** 10-34°C.

**Catalog #:** 91-200-92

**Lot #:** 68267-0000

**Irradiation Date:** 10/13

**Expiration Date:** 09/16

**Country of Origin:** 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.

This product is intended for *Further Manufacturing/Processing 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.

**Sterilization:** The product has been irradiated and dosimetrically release based on ANSI/AAMI/ISO 11137 *Sterilization of healthcare products – Requirements for validation and routine control – Radiation sterilization*.

Sterility Assurance Level: SAL  $10^{-6}$

For detailed information on Mediatech, Inc. material specifications or procedures, please contact our Technical Services department at (800) CELLGRO (235-5476) or via email at [MITechServ@corning.com](mailto:MITechServ@corning.com).

WrittenBy/Date: *Julie Nelson* 16 Oct 2013

Quality Systems Department

Verified By/ Date: *Jacques Ferrero* / *YE*  
16 Oct 2013