

Certificate of Compliance

Description: 3 L Expansion Bag
Gamma Irradiated

Catalog #: 91-200-86
Lot #: 134046
Irradiation Date: 07/13
Expiration Date: 07/15
Country of Origin: USA

Storage: -20 to 40°C.

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.

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.

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*.

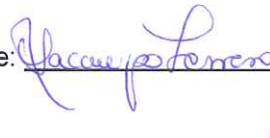
Sterility Assurance Level: SAL 10^{-6}

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.

WrittenBy/Date:

 12 Aug 2013
Quality Systems Department

Verified By/ Date:

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12 Aug 2013