

Certificate of Compliance

Description 10 Liter EVA Bag

Catalog #:

91-200-45

Lot #:

98AU8-0000

Expiration Date:

2022-09

Storage 10 to 34°C

Country of Manufacture:

Mexico

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 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.

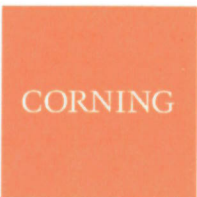
Sterilization: The product has been irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 *Sterilization of healthcare products – Requirements for validation and routine control – Radiation sterilization*.
Sterility Assurance Level: SAL 10⁻⁶

For additional information on this Mediatech product, please contact our Technical Services department at (800) 235-5476 or via email at MTTechServ@corning.com.

Following signatures indicate the above material has met all quality specifications and has been reviewed by a Quality representative.

Written By/Date: VM 23 Oct 2019

Reviewed By/Date: Jacques Ferrero / QI
25 Oct 2019



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