

Certificate of Compliance

Description: Filling Bell Assembly

Catalog #: 91-700-12

Lot #: 79062-0000

Expiration Date: Dec 2017

Storage: 10-34°C

Country of Manufacture: 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 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: Elizabeth Yelmas 20 Jan 2015

Reviewed By/ Date: Ricardo Ferrero / EI
21 Jan 2015

CORNING

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