

## **Certificate of Compliance**

Corning Incorporated - Life Sciences 271 County Route 64 Big Flats NY 14814 USA www.corning.com/lifesciences Refer to website for regional contact information.

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Product Name : BOTTLE, 250mL, SQUARE, POLYCARBONATE, S, BK, 12/24

Catalog Number : 431431 Manufacture Date : 2018-05-30

Lot ID : 15018005

Expiration Date : Unconfirmed Validity

Quality Management System - Complies with the current version of the ISO 9001 Standard.

**Non-Pyrogenic** - Validated per FDA guidelines on Pyrogen and Endotoxins testing. The acceptance level for product is  $\leq 0.1$  EU/ml.

**Sterility** - Product has been sterilized and dosimetrically released per the requirements of ANSI/AAMI/ISO 11137, "Sterilization of health care products- Radiation". Products meet a minimum Sterility Assurance Level (SAL) of  $10^{-5}$ .

**Quality Control Testing** - Representative production samples are collected and inspected in accordance with current applicable product specifications. Inspection records are reviewed and approved by qualified personnel for product release. Key inspections and inline tests are listed below:

Visual Inspection - Pass Packaging Inspection - Pass

- This product met Corning Incorporated - Life Sciences' high standards of quality at the time of batch/lot release.

Elizabeth M (Betty) Hansen

Quality Manager

Elizabeth Hansen

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