# CORNING

## Certificate of compliance

Date of certificate : 2023 - 01 - 05

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CORNING GOSSELIN SAS 123 Rue de Caëstre - CS40019 59529 HAZEBROUCK CEDEX BORRE - FRANCE www.corning.com/lifesciences Refer to website for regional contact information

## **Product description**

Corning Octagonal PET Bottle, 125mL Graduated, 31mm IATA-Validated Screw Cap Sterile, Pre-assembled, 24/Tray, 48/Case

Catalogue number 432331

Lot number 836755

#### **Quality Management System :**

Complies with the current version of the ISO9001 standard.

#### Raw material statement

The Substances Bisphenol A, BSE / TSE, latex, and phthalates are not used or intentionally incorporated in the manufacture of the raw materials or final product.

#### **Sterility Assurance Level**

This product is sterilized using an irradiation method compliant with the requirements of ANSI/AAMI/ISO 11137 to achieve a Sterility Assurance Level (SAL) of 10-6

**Leakproof** - With a torque value of 2,5N.m (22lb.in), this product meets IATA Packaging Instruction 650 requirements to ensure leakproof performance during air transport conditions; however, this is not designed for packaging and transport of UN3373 Biological and Infectious Substances.

**Non-Pyrogenic** - Tested and met the criteria established in the current version of United States Pharmacopeia (USP) Chapter <85> "Bacterial Endotoxins Test." The acceptance level for product is less than 0.1 EU/ml.

**USP Class VI Testing -** All material resin is tested, qualified and shown to be non-toxic as established in the standards USP Class VI Chapter <87>, "Biological reactivity Tests, in Vitro" and Chapter <88>, "Biological Reactivity Tests, in Vivo."

Expiration date 2025/11/01

#### **Expiration statement**

This product is designed to have an expiration date of 3 years from the date of manufacture regarding sterility.

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

Hugues Vanderschelden Plant Quality Manager, Borre vandersch2@corning.com Manufacturing date 2022/11/01

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### Performance testing (AQL)

Inspection based on a statistically significant number of samples towards to internal or agreed specifications that determine Assurance Quality Level. We confirm that product is compliant with ISO993/USP31 : Non-cytotoxic, Endotoxin-free / non-pyrogenic.

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

Hugues Vanderschelden Plant Quality Manager, Borre vandersch2@corning.com

# Manufacturing date 2022/11/01