

CORNING GOSSELIN SAS  
123 Rue de Caëstre - CS40019  
59529 HAZEBROUCK CEDEX  
BORRE - FRANCE

Date of certificate : 2021 - 08 - 25

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### Product description

Octagonal bottle, 500 ml PET na graduated H180 Ø31 & tamper-evident screw cap na, 12/filmed pack, STERILE R

### Catalogue number

431733

### Manufacturing date

2021/06/12

### Lot number

789368

### 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<sup>-6</sup>

### 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

2024/06/01

### Expiration statement

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

### Performance testing (AQL)

Inspection based on a statistically significant number of samples towards to internal or agreed specifications that determine Assurance Quality Level.



Hugues Vanderschelden  
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