

CERTIFICATE OF QUALITY

Product Description: CRYO 3.0ml SS EXT. THREAD / LIP SEAL # 479-1775

Catalog Number: T309-3AVW

Lot Number: 433382323

Sterilization Expiration Date: 11/2023

Country of Origin: VN

Quality System Compliance

The product was subjected to proper manufacturing practices and was produced under the manufacturer's Quality management system. The product was inspected and controlled through whole production processing in accordance with current applicable product specifications and QC SOP. Inspection records were signed off by qualified personnel for product release.

QC Testing

The product is subjected to inspection in accordance with the product specification using the sampling procedures ISO 2859-1:1999. It has been inspected by qualified quality inspectors and released after inspection and testing of determined criteria:

- Clear, no presence of contamination in plastic.
- Visual attributes
- Dimension and volume measurements
- Closure verification
- Leak proof testing in vacuum at 71.3cm Hg
- Gas phase of Liquid Nitrogen resistance

Product Specifications

Material: Polypropylene tube and cap. Resin used in the manufacture conforms to FDA 21 CFR 177.1520 and USP Class VI. Silicone washer seal (Only for models that contains a washer seal)

Temperature Range: -196°C to +121°C Autoclavable at 121°C, for up to 30 minutes.

Sterilization Procedure: The product has been sterilized to meet an established sterility level of SAL 10^{-6} . The Specified Dose of Irradiation for the product is a minimum of 15.6 kGy and a maximum dose of 31.0 kGy. The Radiation Sterilization Validation process is performed by an outside laboratory according to guidelines of ANSI/AAMI/ISO 11137:2013.

BPA Statement: Bisphenol-A (BPA) and Bisphenol-F (BPF) are not used in the manufacture or the formulation of the raw materials and are not expected to be present. However, tests have not been performed for these chemical materials.

Phthalate/DEHP Statement: Phthalates are not added to products as plasticizers. However, traces of phthalates may be present in some products as impurities from catalytic system.

RoHS Compliance: Plastics and colorants are in conformity with CONEG standards for heavy metals.

REACH (SVHC) Statement: The Plastic used is in conformity to REACH standards.

BSE/TSE Statement: Material is BSE/TSE free.

Non-Pyrogenic: Samples of this product have been tested for Endotoxin via LAL Test, levels <0.06 EU/mL

DNase & RNase Free: Certified RNase, DNase, Pyrogen and DNA free.

Cytotoxicity: Testing is conducted to qualify all material resins using ISO 10993 standards for cytotoxicity

Latex Free Statement: Product is latex free.

Storage Conditions: Store at room temperature in normal warehouse conditions; Avoid temperature variations and humidity; Protect from any possible contamination; Protect from any damage to the packaging which could compromise the product sterility

Additional Information: Tubes have printed graduations and writing area. Material has passed MEA testing.

Signed:

Annette Roy
QA Coordinator

Date: 2019-02-04