**Edition Date:** 2018-01-05 Revision Date: 2022-01-13

Revised by: Annette Roy, QA Coordinator

**Product Name: Cryovial®** Catalogue No.: T210-2A

This document replaces any previous version

## 1. Product Description:

> 2ml Cryogenic Vial with Cap: Sterile, disposable, self-standing tube with bottom 2D insert,

external threaded design assembled with washer-seal cap.

2. Packaging:

Case: 5 bags of 100 units / 500 units per case

## 3. Product Specifications:

Material:

• Tube: Polypropylene • Cap: Polypropylene Washer Seal: Silicone

• Bottom 2D insert: Polypropylene

RNase, DNase, Pyrogen and DNA Free

Gamma radiation sterilized at a SAL of 10<sup>-3</sup>; specified dose between 6.5 kGy and 13.5 kGy

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

> Tubes have printed graduations and writing area

2D Datamatrix barcoded Insert on bottom of the tube

## 4. Standards and Conformity:

> ISO 2859-1: Sampling and inspection procedures ➤ FDA: Resin conforms to FDA 21 CFR 177.1520

➤ USP: Resin conforms to USP Class VI

> CONEG / RoHS: Plastics and colorants are in conformity with

CONEG / RoHS standards for heavy metals

> REACH (SVHC): Plastic is in conformity to REACH standards

> LATEX: Material is Latex Free BSE / TSE: Material is BSE / TSE Free

➤ MEA: Material has passed MEA testing

Page 1 / 2 Issue Date: 2017-06-15

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### 5. Quality Assurance:

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

# 6. Traceability:

**▶** Lot No. Composition: 8 or 9 digits

#### > The lot number can be found in one or all of these locations:

- 1. On exterior case label
- 2. On label inserted inside the master case
- 3. On the inner bag

## 7. 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

### 8. Recommended Use:

- Verify proper cap closure when using biohazard material and / or chemical reagents
- > Follow chemical resistance chart recommendations
- For use in automated equipment, follow the equipment manufacturer's instructions
- > Should be used only in the gas phase of Liquid Nitrogen

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Page 2 / 2 Issue Date: 2017-06-15

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