Edition Date: 2007-08-10 Revision Date: 2020-08-25

Revised by: Annette Roy, Regulatory

Catalogue No.: L200-2A Product Name: INO-LOOP™

This document replaces any previous version

1. **Product Description:**

> > 10µl Inoculating Loop: Yellow, Disposable, sterile loop

2. Packaging:

> 100 bags of 10 units / 1 000 units per case Case:

> > (Packaged sterile in safe, tamperproof, zip-lock resealable bags)

3. **Product Specifications:**

Material:

• Loop: High Impact Polystyrene

• Loop Color: Yellow

> Length: 227 mm

Figure 3.5 Gamma radiation sterilized at a SAL of 10⁻³; specified dose between 6.5 kGy and 13.5 kGy

> Temperature range: -80°C to +80°C

➤ Non autoclavable

Standards and Conformity: 4.

> > ISO 2859-1: Sampling and inspection procedures > FDA: Resin conforms to FDA 21 CFR 177.1640 ➢ RoHS: Plastics and colorants are in conformity with

> > RoHS standards for heavy metals

5. **Quality Assurance:**

- > Clear, no presence of contamination in plastic
- Visual attributes
- > Dimension measurements

6. Traceability:

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

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

On exterior case label 1.

2. On label inserted inside the master case

3. On the inner bag

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

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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:

> Smooth and flexible to facilitate uniform streaking without damaging the gel surface.

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Page 2 / 2

Issue Date: 2017-06-15