Edition Date: 2013-04-03 **Revision Date:** 2022-08-08

Revised by: Annette Roy, QA Coordinator

Page 1 / 2

Product Name: HistoTainer™ II Catalogue No.: M961-120FW

This document replaces any previous version

1. **Product Description:**

➤ 120ml Prefilled Specimen Container with White Lid: Disposable, non-sterile

Prefilled with 10% Neutral Buffered Formalin

2. Packaging:

Case: 4 internal trays of 24 units / 96 units per case

(Packaged in sturdy cardboard box with handles for easy carrying)

3. **Product Specifications:**

➤ Material:

• Container: Polypropylene

• White Lid: High Density Polyethylene

- Half prefilled with 10% Neutral Buffered Formalin (SDS available upon request)
- Wide lid ribbed cap for easy opening
- Closure with a unique integrated leak-resistant seal
- ➤ Cap configuration allows insertion of a CapinsertTM (T345 Series) for color-coding

Standards and Conformity: 4.

> ISO 2859-1: Sampling and inspection procedures Resin conforms to FDA 21 CFR 177.1520 Plastic > FDA: > REACH (SVHC): is in conformity to REACH standards

5. **Quality Assurance:**

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

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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. Store locked up. Store in a well-ventilated place. Keep container tightly closed
- Avoid temperature variations and humidity
- Protect from any possible contamination
- Protect from any damage to the packaging

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

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

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