

2013-04-03 2022-08-08 Annette Roy, QA Coordinator

Product Name: HistoTainer[™] II Catalogue No.: M961-60FW

This document replaces any previous version

1. Product Description:

60ml 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 Capinsert[™] (T345 Series) for color-coding

4. Standards and Conformity:

- Sampling and inspection procedures
- > FDA:
- Resin conforms to FDA 21 CFR 177.1520
- REACH (SVHC): Plastic 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



Edition Date: Revision Date : Revised by: 2013-04-03 2022-08-08 Annette Roy, QA Coordinator

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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