

**Product Name: CoreDish®**

**Catalogue No.: M970 series**

This document replaces any previous version

## 1. Product Description:

- **Biopsy Container:** Non-sterile multiple biopsy containers with 30 ml Neutral buffered Formalin
  - M970-D5B-2                      5 compartment                      Breast Biopsy
  - M970-D8P                        8 compartment                      Prostate Biopsy
  - M970-D8UGI                    8 compartment                      Upper GI track Biopsy
  - M970-D12LGI                  12 compartment                    Lower GI track Biopsy
  - M970-D12P                      12 compartment                    Prostate
  - M970-D5                         5 compartment                      General purpose
  - M970-D58                       8 compartment                      General purpose
  - M970-D12                       12 compartment                    General purpose

## 2. Packaging:

- **Case:** 10 units per case (packaged individually)

## 3. Product Specifications:

- **Material:**
  - CoreDish®: Polystyrene
  - O-ring Seal: Silicone
  - Neutral buffered formalin
- Patient identification label on each unit
- Temperature range -80°C to +80°C
- Not autoclavable

## 4. Standards and Conformity:

- **ISO 2859-1:** Sampling and inspection procedures
- **FDA:** Resin conforms to FDA 21 CFR 177.1640
- **CONEG:** Plastics and colorants are in conformity with CONEG standards for heavy metals
- **REACH (SVHC):** Plastic is in conformity to REACH standards
- **LATEX:** Material is Latex Free

## 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:**
  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

## 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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