GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

SUPPLY CHAIN MANAGEMENT

Specification and Packaging Requirement

Product: NCPAP Breathing Circuits (Neonatal)

---

1. Product Specification

1.1 General Description
- Product Name: FISRT224: Neonatal Evaqua 2
- Type: Circuit patient neonatal disposable (single patient use)
- Size: 1.6m
- Shape: Single Limb heated circuit

1.2 Material:
- Predominant materials Polyethylene Adhesion
- Inspiratory Limb: Less condensate due to insulation microcell technology
    - Protection from cool drafts
    - MicroCell technology forms an insultation shield between the cool air outside and water vapor inside.

---

2. Performance Requirements
- Resistance to flow at 2.5L/min as packaged
- Inspiratory: 0.09 cm H2O
- Length of tubing 1.6m
- Compliance 1.3 mL/cm H2O
- Ambient Range 18-26C °C
- Compressible Volume 758 ml
- Maximum chamber: operating pressure 8 kPa
- Duration of Use: 14 days

Compatibility Compatible with MR850 humidifiers

---

3. Packaging Requirements

3.1 Individual Unit Packaging
- Material: Medical-grade, sterile peel-open pouch
- Labeling:
    - Product name & size

- Lot number & expiration date
- Sterility confirmation
- Manufacturer details
- Usage instructions & precautions

3.2 Box Packaging

- Quantity: 10 circuits per box
- Material: Sturdy cardboard
- Labeling:
  - Product specifications
  - Storage conditions
  - Batch number & expiration date
  - Regulatory compliance (e.g., CE Mark, FDA)

3.3 Shipping Carton

- Material: Corrugated cardboard
- Quantity: Multiple boxes per carton (as per order requirement)
- Handling Instructions:
  - Store in a cool, dry place
  - Protect from direct sunlight and moisture
  - Fragile – handle with care

---

4. Regulatory & Compliance

- Sterilization: Ethylene oxide (EtO) or gamma sterilization
- Certifications: CE, FDA, ISO 13485

---

5. Storage & Shelf Life

- Storage Conditions: 10°C – 30°C, dry environment
- Shelf Life: 5 years from manufacture date

24/04/2026