GAUTENG PROVINCE

HEALTH
REPUBLIC OF SOUTH AFRICA

SUPPLY CHAIN MANAGEMENT

Specification and Packaging Requirement

Product: Breathing Circuits (Neonatal)

---

1. Product Specification

1.1 General Description

- Product Name: FISRT265: Neonatal Evaqua 2
- Type: Circuit patient neonatal disposable (single patient use)
- Size: 1.6m
- Shape: Dual 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.
- Expiratory Limb
  - Less condensate with permeable Evaqua technology
  - Protection through a robust wall structure
  - Allows humidity to diffuse out of the breathing circuit freely.

---

2. Performance Requirements

- Resistance to flow at 2.5L/min as packaged
- Inspiratory: 0.09 cm H2O
- Expiratory: 0.07 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

Gauteng Department of health, No 45 Commissioner Street, Johannesburg, 2001.
P O Box 8769, Marshalltown 2107

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