

# **VIAMED Ltd,**

## **Scope**

### **ISO 13485:2016 MDD / 93 / 42 EEC**

**Operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:**

**The design, manufacture and service of: Oxygen Sensors and accessories, Supra-Maximal Peripheral Nerve Stimulator, Simulation Equipment, Infant T-Piece Resuscitators, Apgar Timer and Resuscitation Cabinets. Includes service of Infant T-Piece Resuscitators & Apgar Timer on customer premises.**

**Distribution of CE marked products from other manufacturers.**

**Service of CE marked products from other manufacturers.**

**Service on customer premises of other manufacturers' CE marked products: Radiant Warmers, Air/Oxygen Blenders & Suction Controllers.**

#### **Including the Product Ranges:**

**Tom Thumb, Microstim, Apgar Clock, Foetal Heart Simulator, Oxygen Sensors**

Oxygen Sensors, T-Adaptors, Pole Mount Bracket, Rail Mount Bracket, Flowmeter, Blender, NIST hose Air/Oxygen, Radiant Warmer, Phototherapy Eye Masks, Patient circuit, Connectors, Universal mounting clamps, Adapter for tyre chucks, Oxygen Sensors and Monitors, Medical Automotive and Industry, Suction controllers, Suction jars, Flowmeters, Suction clear tubing, Oxygen hoses, Air hoses, Bird Blender Servicing, Finger Pulse Oximeters, Pulse Oximeters, SpO2 Silicone Finger Sensors, SpO2 Wrap Sensor, Pulse Oximetry Ear Sensors, Disposable SpO2 Sensors, Universal mounting plate with V mounts, Temperature probe - Oesophageal/Rectal, Temperature probes - Skin contact, Flow sensors, OEM Flow Modules, Mainstream Capnographs, Sidestream Capnographs, Multigas Capnographs, Nomo adapters, Nomoline Phase II, Disposable sampling lines, CO2 Nasal Sampling Cannula, VersaStream - Nasal Prong Sampling Line, VersaStream - Nasal Sampling Lines, VersaStream - Oral/Nasal Sampling Lines, VersaStream - Airway Adapters, Standard Gas Sampling Lines, AlcoTrue Breath Testers, Carrying cases, Nellcor DS-100A Digit X1 SpO2 fingers, NeoPEEP neonatal single patient use, Single use silicone round facemasks, Sensor wraps, Removable I.D. Bracelets Newborn, Removable I.D. Bracelets Premie, Posey IV Armboard - Infant, Posey IV Armboard - Paediatric, Posey IV Shield, Posey Secure Sleeve, Posey Elbow Splints, Posey Foam Trach Ties, Rail mounted V socket, Tapered connectors 10 per pack, 1l VacSax canister with V mount, 1l VacSax standard bore liners, DryMax Neo, Pulse Oximetry Ear Clip/Lingual Clip, Cabinets/Furniture to accommodate infant resus devices, Automotive oxygen monitors, sensors and accessories, Industry oxygen monitors, sensors and accessories.

**For Exclusions to ISO 13485:2016 See  
VM3COP02.01 Exclusions to Viamed ISO 13485:2016 boundaries of ISO**