

Lists and Definitions of the Device

A. Identification of Distributor

Marshall Airway Products Limited

Suite 3H1 St Peters Park, Cobblers Way, Radstock BA3 3BX

Tel: 0845 612 8888

Fax: 0845 612 8889

B. Identification of Manufacturing Site

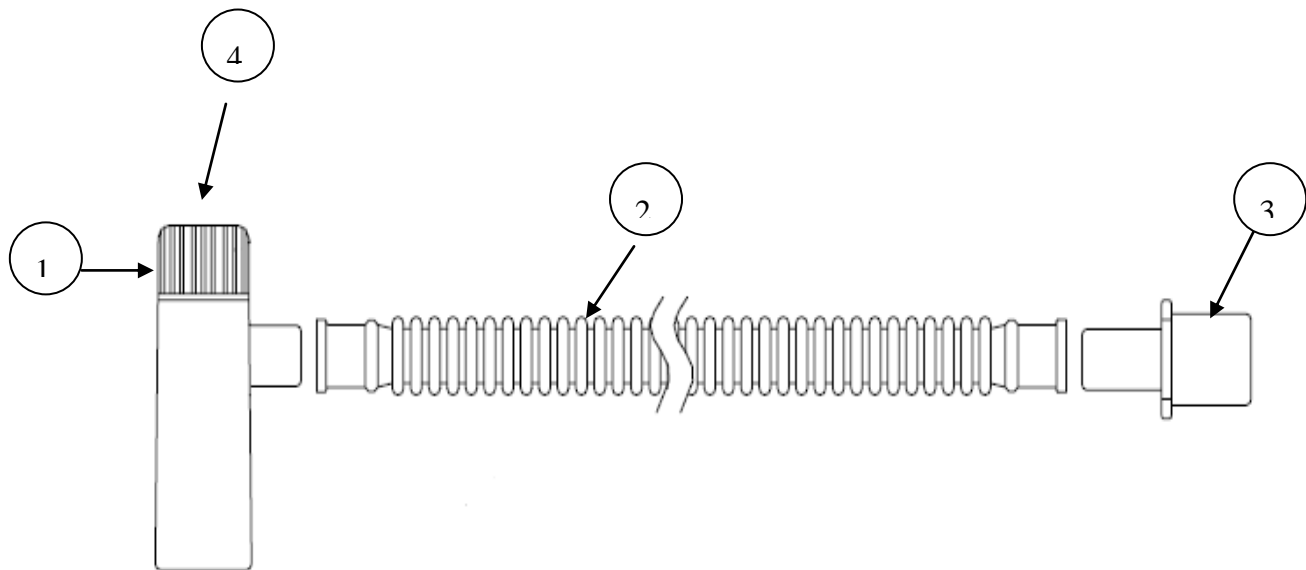
Company Name: Three Lions Limited

Address: 21 Qunyi Industrial Park , Heng Shan Road , Kunshan , P.R. China

Tel: 86 0512 5700 0981

Fax: 86 0512 5700 8935

C. Product Description and Intended Use



- (1) PEEP valve adjustable (0-15 mbar) Colour of cap and body of NeoPEEP Valve: Pink or Blue
- (2) Disposable hose; L: 1000 / 1300 \pm 50 mm ID: about 10mm (Transparent)
- (3) Connector to device; OD: 15mm according to [ISO5356-1]

The NeoPEEP™ is a Single Patient Use Neonatal Resuscitation Circuit. At the T-piece of the NeoPEEP™ the PEEP can be regulated by turning the cap (1) clockwise (increasing) or counter clockwise (decreasing).

The air flow (Peak Inspiratory Pressure) from the device can be directed to the child by covering the hole of the T- piece (4) with a finger /thumb. During expiration when the hole is not covered,

the demanded backpressure (PEEP) will be applied by the opening inside the T-piece.

This process of covering/ uncovering the hole of the T- piece (4) with a finger /thumb, regulates the Inspiratory and Expiratory time (Breaths per minute) including PEEP pressure on expiration.

Peak Inspiratory Pressure (PIP)

The **NeoPEEP®** Single Use Resuscitation Circuit will safely inflate the baby's lungs to provide controlled and accurate Inspiratory pressure. This will provide oxygenation of the lungs (according to the settings on the resuscitation device used) by delivering consistent PIP with each breath. Using the **NeoPEEP®** 'T'-Piece, the risks associated with under or over inflation at uncontrolled pressures will be avoided when used in accordance with the **NeoPEEP®** Single Use Resuscitation Circuit Instructions for Use.

Positive End Expiratory Pressure (PEEP)

The **NeoPEEP®** Single Use Resuscitation Circuit will allow the user to regulate the Functional Residual Capacity (FRC, the volume of gas contained in the lung after a normal expiration) by providing a consistent PEEP (pre set by the user in accordance with the **NeoPEEP®** Single Use Resuscitation Circuit Instructions for Use) throughout the resuscitation process.

PEEP allows a continuous pressure in the lungs after expiration; this process will prevent the lungs from entirely deflating which can cause additional complications to the infant.

D. Notified body

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E. Operating Temperature and Storage Temperatures

Operating Environmental Temperature Limits: -18°C to +50°C

Storage Environmental Temperature Limits: -40°C to +60°C