



Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 17 07 63744 016

Manufacturer:

Wenzhou Rising Industrial Co., Ltd

No.345, Xincheng Road, Wenzhou
325000, China

EC-Representative:

Shanghai International Holding Corp. GmbH (Europe)

Eiffestraße 80
20537 Hamburg
GERMANY

Product

Category(ies):

Silicone/SEBS/PVC Manual Resuscitators
(Including Mask, Positive End-Expiratory Pressure Valve,
Oxygen Tube, Reservoir Bag, Mouth opener,
Oropharyngeal airway, Manometer),
Resuscitation Mask, Continuous Positive Airway Pressure
Mask/Non-invasive Ventilation Mask, Simple Oxygen Mask,
Venturi Mask, Non-Rebreathing Mask,
Aerosol Mask w/Nebulizer,
Breathing Circuit (Including Mask,
Elbow Connector, Y piece, Corrugate Tubing,
Collapsible Tubing, Water Trap, Straight Connector, HMEF),
Anesthesia Circuit (Including Mask, Elbow Connector
w/Luer port & cap, Y piece, Corrugate Tubing,
Collapsible Tubing, Straight Connector, Breathing Bag,
Bacterial Filter, gas sampling line),
Laryngeal Mask Airway, Anesthesia Mask



The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.:

SH17176EXT01

Valid from:

2017-10-01

Valid until:

2022-09-30

Date, 2017-08-01

Stefan Preiß



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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