



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



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 094928 0004 Rev. 03

Manufacturer:

Bonree Medical Co., Ltd.

No.4 Longzhu Garden, Wanmu Industrial Estate
Nanlang
528451 Zhongshan, Guangdong
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Oxygen Masks, Aerosol Masks, Multi-vent Masks, Non-
Rebreathing Masks, Tracheostomy Masks, Nasal
Oxygen Cannulas, Suction Catheters, Stomach Tubes,
Feeding Tubes, Yankauer Suction Sets, Endotracheal
Tubes, Reinforced Endotracheal Tubes, Endobronchial
Tubes, Laryngeal Masks Devices, Intubating Stylets,
Endotracheal Tube Introducers(bougie), Guidewires,
Nelaton Catheters, Ureteral Stent Sets, Percutaneous
Nephrostomy Sets, Ureteral Access Sheaths,
Nebulizers, Nasal Oxygen Catheters, Disposable Air
Cushion Face Masks, Endotracheal Tubes with
Evacuation Lumen, Ureteral Catheters, Intermittent
Catheter Kits, Tracheostomy Tubes, Urodynamic
catheters, Stone Retrieval Baskets, Urethral Dilators,
Ureteral Dilators, Ureteral Dilation Balloon Catheters,
Nasal CO₂ Sampling Cannulas, CO₂ Sampling and O₂
Delivery Masks, Medical Video Endoscopes

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.:

SH191058EXT01

Valid from:

2020-02-10

Valid until:

2024-05-26

Date, 2020-02-10

Christoph Dicks
Head of Certification/Notified Body

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®



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Facility(ies):

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Nanlang, 528451 Zhongshan, Guangdong,
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