



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 CO<sub>2</sub> Sampling Cannulas, CO<sub>2</sub> Sampling and O<sub>2</sub>  
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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 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT



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**Facility(ies):**

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 Nanlang, 528451 Zhongshan, Guangdong,  
 PEOPLE'S REPUBLIC OF CHINA**

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