



Deutsche  
Akkreditierungsstelle  
D-ZM-11321-01-00



Product Service

# Certificate

No. Q5 094928 0005 Rev. 04

**Holder of Certificate:**

**Bonree Medical Co., Ltd.**

1st floor of Building No.2  
Building No.4, Longzhu Village Economic Estate  
Longzhu Avenue  
Nanlang  
528451 Zhongshan, Guangdong  
PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**



**Scope of Certificate:**

Design and Development, Production and Distribution of 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, Latex Foley Catheters, Silicone Foley Catheters, Foley Catheter Trays, Oropharyngeal Airways, Nasopharyngeal Airways, Rectal Catheters, 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, Medical Video Endoscopes Image Processor

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 094928 0005 Rev. 04](http://www.tuvsud.com/ps-cert?q=cert:Q5 094928 0005 Rev. 04)

**Report No.:**

SH25105801

**Valid from:**

2025-08-01

**Valid until:**

2028-07-31

**Date,**

2025-04-24

Christoph Dicks

Head of Certification/Notified Body



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**Applied Standard(s):** ISO 13485:2016  
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)  
Medical devices - Quality management systems -  
Requirements for regulatory purposes

**Facility(ies):** **Bonree Medical Co., Ltd.**  
1st floor of Building No.2, Building No.4, Longzhu Village  
Economic Estate, Longzhu Avenue, Nanlang, 528451 Zhongshan,  
Guangdong, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

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