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Zentralstelle der Länder  
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bei Arzneimitteln und  
Medizinprodukten  
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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 086250 0018 Rev. 00**

**Manufacturer:** **Ningbo Luke Medical Devices Co., Ltd.**

Gujiayan, Yangming Road  
315400 Yuyao City, Zhejiang Province  
PEOPLE'S REPUBLIC OF CHINA

**EC-Representative:** Shanghai International Holding Corp. GmbH (Europe)  
Eiffestraße 80, 20537 Hamburg, GERMANY

**Product Category(ies):** Laryngeal Mask Airways,  
Stomach Tubes, Drainage Tubes,  
Endotracheal Tubes, Oxygen Masks,  
Suction Catheters, Nasal Oxygen Cannulas,  
Breathing Circuits,  
Heat and Moisture Exchangers,  
Breathing System Filters,  
Manual Resuscitators,  
Wound Drainage Systems,  
Infusion Sets with Precision Filters for Single-Use,  
Double Lumen Endobronchial Tubes,  
Single-Use Anesthesia Kits,  
Urinary Catheterization Collection Kits,  
Disposable Endobronchial Blocker Tubes,  
Anesthesia Masks, Catheter Mounts,  
Suction Tubing with Yankauer Handle,  
Nebulizer Masks, Tracheostomy Tubes.

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.:** SH1865109  
**Valid from:** 2019-05-07  
**Valid until:** 2021-01-03

**Date,** 2019-05-07

Stefan Preiß

TÜV SÜD  
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT

