



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 074897 0011 Rev. 02**

**Manufacturer:** NINGBO HI-TECH UNICMED  
 IMP. & EXP. CO., LTD.  
 11/F, GREEN TOWN LVYUAN TOWER  
 588 CANGHAI ROAD  
 315040 NINGBO  
 PEOPLE'S REPUBLIC OF CHINA

**Product Category(ies):** Wound Drainage System With and without Trocar, Suction Catheters, Stomach Tubes, Oxygen Mask With Reservoir Bag, Nasal Cannula, Suction Connection Tube With Yankauer Handle, Nebulizer Mask, Blood Lancets, Simple Oxygen Mask, Disposable Surgical Blades(with and without handle), Digital Thermometers, C.P.R. Mask, Blood Pressure Monitors, Tracheal Tubes, Reinforced Endotracheal Tubes, Disposable Air Cushion Face Masks, Laryngeal Mask Devices, Sterile Latex Surgical Gloves, Vacuum Blood Collection Needles for Single use.

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.:** SH19635EXT01  
**Valid from:** 2019-09-23  
**Valid until:** 2024-05-26

**Date,** 2019-09-23

Stefan Preiß  
 Head of Certification/Notified Body

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 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT





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