











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 104141 0003 Rev. 00**

**Manufacturer:**

**Guangzhou Orcl-Medical Co., Ltd.**

Building 4 (Plant A-7)  
No.100 Beilong Rd.  
Dagang Town, Nansha District  
511470 Guangzhou, Guangdong  
PEOPLE'S REPUBLIC OF CHINA



**Product  
Category(ies):**

**Reinforced Endotracheal Tube, Endotracheal Tube,  
Tracheostomy Tube, Endobronchial Tube, Silicone  
Foley Catheter, Stomach Tube, Laryngeal Mask, Air  
Cushion Mask, Oxygen Mask, Connecting Tube  
with Yankauer Handle, Nasal Oxygen Cannula,  
Tracheostomy Mask, Vacuum Suction Ball, Y-type  
Irrigation Tube, Suction Tube**

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.:** GZ1934901

**Valid from:** 2020-02-19

**Valid until:** 2024-05-26

**Date,** 2020-02-19

Christoph Dicks  
Head of Certification/Notified Body









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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 I in sterile conditions, sterilised systems or procedure packs)

**No. G2S 104141 0002 Rev. 00**

## Facility(ies):

Guangzhou Orcl-Medical Co., Ltd.  
Building 4 (Plant A-7), No.100 Beilong Rd., Dagang Town, Nansha  
District, 511470 Guangzhou, Guangdong, PEOPLE'S REPUBLIC  
OF CHINA



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