



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 078455 0020 Rev. 00

Manufacturer:

Zhanjiang Star Enterprise Co., Ltd.

No. 1, West Jinhua Road
Mazhang District
524094 Zhanjiang
PEOPLE'S REPUBLIC OF CHINA

**Product
Category(ies):**

**Foley Catheter (latex), Nelaton Catheter (latex),
Endotracheal Tubes, Anesthesia Kits,
Suction Catheter for Single Use
in the Respiratory Tract,
Disposable Urethral Catheterization Set,
Urethral Catheters (PVC), Stomach Tube (PVC),
Reinforced Endotracheal Tube,
Nebulizer, Laryngeal Mask**

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.:

SH19090EXT02

Valid from:

2019-10-29

Valid until:

2024-05-26

Date,

2019-10-29

Christoph Dicks
Head of Certification/Notified Body



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Facility(ies):

**Zhanjiang Star Enterprise Co., Ltd.
No. 49 Jinchuan Road, 524094 Zhanjiang,
PEOPLE'S REPUBLIC OF CHINA**

**Zhanjiang Star Enterprise Co., Ltd.
No. 1, West Jinhua Road, Mazhang District, 524094
Zhanjiang, PEOPLE'S REPUBLIC OF CHINA**

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT