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

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 078455 0018 Rev. 00

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

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

Product Category(ies): **Urethral Catheters (silicone), Tracheostomy Tubes for Single Use**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: SH19090EXT01

Valid from: 2019-05-17
Valid until: 2024-05-16

Date, 2019-05-17

Stefan Preiß

Digitally signed by Potînga Stela
Date: 2021.04.12 11:54:19 EEST
Reason: MoldSign Signature
Location: Moldova

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD
A4 / 07.17

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

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 078455 0018 Rev. 00

Facility(ies):

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

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

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD
A4 / 07.17

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 078455 0017 Rev. 01

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

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of Foley Catheters, Nelaton Catheters, Endotracheal Tubes, Drainage Bags, Urethral Catheterization Sets, Male External Catheters, Latex Stomach Tubes, T-Tube and Basic Dressing Sets, Suction Catheters for Single Use in the Respiratory Tract, Tracheostomy Tubes for Single Use, Urethral Catheters (Silicone), Urethral Catheters (PVC), Stomach Tubes (PVC), Reinforced Endotracheal Tubes, Anesthesia Kits, Mouth Gags (Mouth Opener), Endotracheal Tube Holders, Male External Catheters (Silicone) /Silicone Condom Catheters, Nebulizers and Laryngeal Masks**

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). See also notes overleaf.

Report No.: SH1909019
Valid from: 2019-09-03
Valid until: 2022-08-31

Date, 2019-09-03

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD
A4 / 07.17

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 078455 0017 Rev. 01

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

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 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany