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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT



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



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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
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Respiratory & Anaesthesia

The respiratory and anaesthetic products are to be inserted to establish and thus maintain an airway for emergency, collecting patients' secretion, regulating breathing and facilitating respiratory disease's atomization.

Product Series :

1. Endotracheal Tube Without Cuff: standard, reinforced and preformed (Material: PVC)
2. Endotracheal Tube With Cuff: standard, reinforced, preformed and suction (Material: PVC)
3. Endotracheal Tube Set (can collocate it according to different requirement)
4. One Way Laryngeal Mask (Material: PVC and silicone)
5. Tracheostomy Tube Without Cuff: standard and reinforced (Material: PVC)
6. Tracheostomy Tube With Cuff: standard, reinforced and suction (Material: PVC)
7. Endotracheal Tube Holder: used for holding the Endotracheal Tube (Material: PP)
8. Suction Catheter: type I and type II (Material: PVC and silicone)
9. Oxygen Cannula: one way and two way (Material: PVC and silicone)
10. Nebulizer: pediatric, adult size (Material: PVC and PP)
11. Mouth Opener (Material: PP)



Cat.-No.:	Size:
2021120 00	ID 2.0
2021125 00	ID 2.5
2021130 00	ID 3.0
2021135 00	ID 3.5
2021140 00	ID 4.0
2021145 00	ID 4.5
2021150 00	ID 5.0
2021255 00	ID 5.5
2021260 00	ID 6.0
2021265 00	ID 6.5
2021270 00	ID 7.0
2021275 00	ID 7.5
2021280 00	ID 8.0
2021285 00	ID 8.5
2021290 00	ID 9.0
2021295 00	ID 9.5
2021210 00	ID 10.0

Endotracheal Tube standard

without cuff
murphy
for anaesthesia and intensive care
X-ray



Cat.-No.:	Size:
2022125 02	ID 2.5
2022130 02	ID 3.0
2022135 03	ID 3.5
2022140 03	ID 4.0
2022145 05	ID 4.5
2022150 05	ID 5.0
2022255 05	ID 5.5
2022260 10	ID 6.0
2022265 10	ID 6.5
2022270 12	ID 7.0
2022275 12	ID 7.5
2022280 15	ID 8.0
2022285 15	ID 8.5
2022290 22	ID 9.0
2022295 22	ID 9.5
2022210 22	ID 10.0

Endotracheal Tube standard

with cuff
murphy
for anaesthesia and intensive care
high volume, low pressure
X-ray