



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

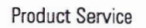
Valid until:

2024-05-16

Date,

2019-05-17

Stefan Preiß



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



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:



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

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

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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