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Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
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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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No. 1, West Jinhua Road, Mazhang District, 524094  
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