



## 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:** 



Design and Development, **Scope of Certificate:** 

**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: Valid until:

2019-09-03 2022-08-31

Date.

2019-09-03

Stefan Preiß

1. Purnil

Head of Certification/Notified Body

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EN ISO 13485:2016 Applied Standard(s):

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,

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