



# Certificate

No. Q5 078455 0017 Rev. 02

**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 and production and distribution of sterile Non-active non-implantable devices for anaesthesia, emergency and intensive care 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, Silicone Stomach Tube, Hydrophilic Urinary/Urethral Catheter, Percutaneous Tracheostomy Set (Kit)  
Production and distribution of sterile Non-active non-implantable devices for anaesthesia, emergency and intensive care Malecot Urine Drainage Catheter, Hysterosalpingography Catheter (HSG catheter)

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). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 078455 0017 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5 078455 0017 Rev. 02)

**Report No.:** SH2209001  
**Valid from:** 2023-02-28  
**Valid until:** 2025-08-31

**Date,** 2023-02-28

Christoph Dicks  
Head of Certification/Notified Body

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## 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. 1, West Jinhua Road, Mazhang District, 524094 Zhanjiang,  
PEOPLE'S REPUBLIC OF CHINA

Design and development and production and distribution of sterile  
Non-active non-implantable devices for anaesthesia, emergency  
and intensive care 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, Silicone Stomach Tube, Hydrophilic  
Urinary/Urethral Catheter, Percutaneous Tracheostomy Set (Kit)  
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devices for anaesthesia, emergency and intensive care Malecot  
Urine Drainage Catheter, Hysterosalpingography Catheter (HSG  
Catheter)

### Zhanjiang Star Enterprise Co., Ltd.

No. 49 Jinchuan Road, 524094 Zhanjiang, PEOPLE'S REPUBLIC  
OF CHINA

Production of sterile Non-active non-implantable devices for  
anaesthesia, emergency and intensive care Foley Catheters,  
Nelaton Catheters, Urethral Catheterization Sets, Male External  
Catheters, Latex Stomach Tubes, T-Tube, Hydrophilic  
Urinary/Urethral Catheter, Malecot Urine Drainage Catheter,  
Hysterosalpingography Catheter (HSG Catheter)