ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q6 005225 0001 Rev. 04

Holder of Certificate: **Hangzhou Primecare Medical Co., Ltd.**
Room 408-409, Zancheng Center West
Shangcheng District
310008 Hangzhou
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate:

Manufacture and Distribution of Sterile and Non-sterile Urine Bag, Enteral Feeding Set, Urine Meters, Urinary Catheterization/Collection Kits, Catheter Care Kit, Surgical Procedure Pack, Dressing Change Tray, Dialysis Kit, IV Start Kit, Suture Remove Kits, Irrigation Tray, Tracheostomy Care/Cleaning Kits, Specimen Container, Ear/Ulcer Syringe, Enema Set, Suction Flexible Yankauer, Suction Catheter Kit, Convenient Kits, Suture Pack, Urine Collector Pediatric, Sterile Pre-filled Syringe, Pre-filled Saline Flush Syringe, Lubricate Gel

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q6 005225 0001 Rev. 04

Report No.:	SH24132003
Valid from:	2024-12-04
Valid until:	2027-12-03

Date, 2024-11-29

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q6 005225 0001 Rev. 04

Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

Facility(ies):

Hangzhou Primecare Medical Co., Ltd.
Room 408-409, Zancheng Center West, Shangcheng District, 310008 Hangzhou, PEOPLE'S REPUBLIC OF CHINA

Manufacture and Distribution of
Sterile and Non-sterile Urine Bag, Enteral Feeding Set, Urine Meters, Urinary Catheterization/Collection Kits, Catheter Care Kit, Surgical Procedure Pack, Dressing Change Tray, Dialysis Kit, IV Start Kit, Suture Remove Kits, Irrigation Tray, Tracheostomy Care/Cleaning Kits, Specimen Container, Ear/Ulcer Syringe, Enema Set, Suction Flexible Yankauer, Suction Catheter Kit, Convenient Kits, Suture Pack, Urine Collector Pediatric, Sterile Pre-filled Syringe, Pre-filled Saline Flush Syringe, Lubricate Gel

Primecare Medical (Suzhou) Co.,Ltd.
Building A1/A4, No. 2 Zengfu Road, Guli Development Zone, 215532 Changshu City, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

Manufacture and Distribution of
Sterile and Non-sterile Urinary Catheterization/Collection Kits, Catheter Care Kit, Surgical Procedure Pack, Dressing Change Tray, Dialysis Kit, IV Start Kit, Suture Remove Kits, Irrigation Tray, Tracheostomy Care/Cleaning Kits, Specimen Container, Ear/Ulcer Syringe, Enema Set, Suction Flexible Yankauer, Suction Catheter Kit, Convenient Kits, Suture Pack, Urine Collector Pediatric, Sterile Pre-filled Syringe

Primecare Medical (Huzhou) Co.,Ltd
No. 398 Guang Yuan Road, Wu Xing District, 313099 Huzhou, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA

Manufacture and Distribution of Sterile and Non-sterile Urine Bag, Enteral Feeding Set, Sterile Pre-filled Syringe, Pre-filled Saline Flush Syringe, Lubricate Gel

.

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®