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

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 095267 0008 Rev. 01

Holder of Certificate: **SEPLOU, INC.**
203 Chandler Walk
Loganville, GA 30052
USA

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of Nelaton Catheter, Latex Foley Catheter, 100% Silicone Foley Catheter, Guidewire, Ureteral Stent Set, Percutaneous Nephrostomy Set, Ureteral Access Sheath, Ureteral Catheters, Ureteral Dilation Balloon Catheters, Urodynamic Catheters, Stone Retrieval Baskets, Urethral Dilators, Ureteral Dilators Production and Distribution of Urine Bag, Surgical Film**

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.: SH19106904

Valid from: 2019-10-10
Valid until: 2022-10-09

Date, 2019-09-30

Stefan Preiß
Head of Certification/Notified Body

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

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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):

SEPLOU, INC.
203 Chandler Walk, Loganville, GA 30052, USA

SEPLOU CO., LTD.
Rm.1302, Bldg.2, New City Time Square, 111 Xintang Road, Jianggan, 310020 Hangzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

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