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

TÜV SÜD
Product Service

Certificate

No. Q6 079078 0013 Rev. 01

Holder of Certificate:

Hangzhou Formed Medical Devices Co., Ltd.
Building 3, No. 292 Gonghe North Road, Xindeng Town
Fuyang District
311404 Hangzhou
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

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

Scope of Certificate:

Production and Distribution of Laryngeal Mask, Tracheal Tube Introducer, Catheter Mount, Hemorrhoidal Device, Endotracheal Tube, Naso-Pharyngeal Airway, Oral-Pharyngeal Airway, Feeding Tube, Oxygen Mask with Reservoir Bag, Nasal Cannula, Oxygen Mask, Nebulizer kit, Silicone Mask, Nasogastric Tube, Suction Tubing with Yankauer Handle, Intubating Stylet, Venturi Mask, Anaesthetic Mask, Gastric Calibration Tube, Nelaton Catheter, Hydrophilic Urinary Catheter, Catheterization Kit, Suction Catheter, Urine Bag, Foley Catheter, Breathing System Filter, Disposable Breathing Circuit, Suction Reservoir, Drainage Tube, Wound Drainage System, Stomach Tube, Heat and Moisture Exchanger, Drainage Bag, Hydrophilic Urinary Catheter Kit, Ileostomy 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 (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Digitally signed by Perminov Andrei
Date: 2021.12.23 12:17:21 EET
Reason: MoldSign Signature
Location: Moldova

Report No.: SH19104104

Valid from: 2019-09-23
Valid until: 2022-08-04

Date, 2019-09-23

Stefan Preiß
Head of Certification/Notified Body

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

TÜV®

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

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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):

Hangzhou Formed Medical Devices Co., Ltd.
Building 3, No. 292 Gonghe North Road, Xindeng Town, Fuyang District, 311404 Hangzhou, PEOPLE'S REPUBLIC OF CHINA

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