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

Product Service

Certificate

No. Q5 066149 0020 Rev. 02

Holder of Certificate: **HANGZHOU FUSHAN MEDICAL APPLIANCES CO., LTD.**
No. 1288 South Jinxi Road
Linglong Industrial Park
Lin'an District
311301 Hangzhou City, Zhejiang Province
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

tuv-sud.com/ps-cert

Digitally signed by Jighili Tatiana
Date: 2022.04.21 14:12:02 EEST
Reason: MoldSign Signature
Location: Moldova

Scope of Certificate: **Design and Development, Production and Distribution of PEG Kit, Drainage Kit, Disposable Central Venous Catheter and Kits, Mini-button Gastrostomy Tube Kit, Double Lumen Endobronchial Tube, Disposable Hemodialysis Catheter Kit.**
Production and Distribution of Silicone Urethral Catheter, Silicone Reservoir, Laryngeal Mask Airway, Lacrimal Dilation Tube, Miniature Infusion Pump, Oxygen Tube, Silicone Urinary Catheter, Rectal Tube, Stomach Tube, Nasogastric Tube, Trocar, Tracheal Tube, Drainage Tube, Nebulizer, Supra Laryngeal Airway, Mask, Urine Bag, Suction Tube Kit, Yankauer Handle, Resuscitator, Guedel/Oropharyngeal Airway, Intravenous Catheter, Infusion Access Adapter, Gastrostomy Tube, Enteral Feeding Bag, Breathing Trainer, Stoma Stoppers, Pharachute Supralaryngeal Airway (PSA) , Pessary, Colostrum Collection Kit, Stapler-Bioabsorbable Skin Closure System, Catheter Dressing, Silicone Foley Catheter Kit, Penrose Tube, Catheter Cap, Nasal Pharyngeal Airway, Silicone Seal, Fluid Management Pack, Latex Foley 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). See also notes overleaf.

Report No.: SH2051201

Valid from: 2020-07-01
Valid until: 2023-06-30

Date, 2020-07-01

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
TÜV SÜD
A4 / 07.17

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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 FUSHAN MEDICAL APPLIANCES CO., LTD.
No. 1288 South Jinxi Road, Linglong Industrial Park, Lin'an District, 311301 Hangzhou City, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA

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