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

TÜV SÜD
Product Service

Certificate

No. Q6 047985 0026 Rev. 01

Holder of Certificate: **Wenzhou K.L.F. Medical Plastics Co., Ltd**
No. 8 Huangshan South Road
Wenzhou Industrial Park
325038 Wenzhou, Zhejiang Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Wenzhou K.L.F. Medical Plastics Co., Ltd
No. 8 Huangshan South Road, Wenzhou Industrial Park, 325038
Wenzhou, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: Production and Distribution of
Sterile Syringe for Single Use, Infusion Set for Single Use, Blood Transfusion Set for Single Use, Haemostatic Forcep for Single Use, Burette Infusion Sets for Single Use, Suction Connecting Tube with and without Yankauer, Suction Pumps of Negative Compressive Stress for Single Use, Injection Caps and Valves, Scalp Vein Set for Single Use, Sterile Irrigation Systems, Caps, Disposable Scrub Brush, Withdrawal Cannula for Single Use, 3-way stopcock, Extension set for single use, Infusion sets for infusion pump

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

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.

Report No.: SH1818517

Valid from: 2019-03-29
Valid until: 2022-12-31

Date, 2019-03-29

Stefan Preiß

TÜV®

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