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

Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 044803 0033 Rev. 05

Holder of Certificate: **Jiangxi Hongda Medical Equipment Group Ltd.**
39 South Shengli RD, Jinxian County
331700 Nanchang, Jiangxi Province
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate:

Design and Development, Production and Sales of Infusion sets for single use, Transfusion sets for single use, Syringes for single use, Sterile needles for single use, scalp vein sets for single use, Blood collection needles for single use, Urine Bag for Single Use, Sterile Single-Use Dental Injection Needles, Vagina Dilator for Single Use, Sterile Autodisable Syringe for Single Use, Disposable Suction Catheter for use in Respiratory Tract, Disposable Stomach Catheter, Single-use Sterile rubber surgical gloves, Single-use medical examination gloves, Disposable sterile needle retractable safety syringe, IV Cannula for single use, Foley Catheter for single use, Extension tube for single use, Endotracheal tube for single use, A.V. fistula needle sets for single use, Burette-type infusion sets for single use, Heparin cap for single use, Sterile insulin syringe for single use, Nasal oxygen cannula for single use, Blood Tubing Sets for Hemodialysis, Feeding tube for single use, Safety scalp vein sets for single use, High-pressure Angiographic syringes and Accessories for single use, Insulin pen needle for single use, Infusion pump for single use, Hollow Fiber Hemodialyzer, Single-use lightproof infusion set, Single-use protective clothing for medical use, Single-use medical surgical face mask, Single-use medical protective face mask, Single-use medical face mask, Single-use Syringe with Catheter tip, Single-use surgical clothing, Single-use sterile dialysis care kit, Single-use enteral feeding infusion set.
Design and Development, Production and Sales of In Vitro Diagnostic Consumables (Vacuum Blood Collection Tubes for Single Use).

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). 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:Q5 044803 0033 Rev. 05

Report No.: BJ25089301
Valid from: 2025-07-01
Valid until: 2028-06-30

Date, 2025-06-25

Christoph Dicks
Head of Certification/Notified Body

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

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

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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):

Jiangxi Hongda Medical Equipment Group Ltd.
39 South Shengli RD, Jinxian County, 331700 Nanchang, Jiangxi Province, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and sales of Syringes for single use, Sterile needles for single use, Scalp vein sets for single use, Safety scalp vein sets for single use, Blood collection needles for single use, Urine Bag for single use, Sterile single-use Dental injection needles, Vagina Dilator for single use, Sterile Autodisable Syringe for single use, Single-use sterile rubber surgical gloves, Single-use medical examination gloves, Disposable sterile needle retractable safety syringe, IV Cannula for single use, Foley Catheter for single use, Heparin cap for single use, Sterile insulin syringe for single use, A.V. fistula needle sets for single use, Blood tubing sets for hemodialysis, High-pressure Angiographic syringes and Accessories for single use, Infusion pump for single use, Insulin pen needle for single use, Single-use Syringe with Catheter tip, Single-use sterile dialysis care kit.
Design and Development and sales of Infusion sets for single use, Transfusion sets for single use, Disposable Suction catheter for use in Respiratory Tract, Endotracheal tube for single use, Disposable Stomach Catheter, Extension tube for single use, Burette-type infusion sets for single use, Nasal oxygen cannula for single use, Feeding tube for single use, Hollow Fiber Hemodialyzer, Single-use lightproof infusion set, Single-use protective clothing for medical use, Single-use medical surgical face mask, Single-use medical protective face mask, Single-use medical face mask, Single-use surgical clothing, Single-use enteral feeding infusion set.
Design and Development, Production and Sales of In Vitro Diagnostic Consumables (Vacuum Blood Collection Tubes for Single Use).

Jiangxi Hongda Medical Equipment Group Ltd.
No. 188 Chuangye Street, Jinxian County, 331700 Nanchang, Jiangxi Province, PEOPLE'S REPUBLIC OF CHINA

Production of Infusion sets for single use, Transfusion sets for single use, Disposable Suction catheter for use in Respiratory Tract, Endotracheal tube for single use, Disposable Stomach Catheter, Extension tube for single use, Burette-type infusion sets for single use, Nasal oxygen cannula for single use, Feeding tube for single use, Hollow Fiber Hemodialyzer, Single-use lightproof infusion set, Single-use protective clothing for medical use, Single-use medical surgical face mask, Single-use medical protective face mask, Single-use medical face mask, Single-use surgical clothing, Single-use enteral feeding infusion set.

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