



Certificate

No. Q5 003509 0004 Rev. 01

Holder of Certificate: **Zibo Qray International Co., Ltd.**
No.77 Zhanghuan Road
255000 Zibo City, Shandong
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: Design, Development, Production and Distribution of Disposable Infusion Pump
Production and Distribution of Simple Oxygen Mask, Nebulizer With Mask, Nasal Oxygen Cannula, Sterile Hypodermic Syringes for Single Use, Sterile Hypodermic Needles for Single Use, Infusion Sets for Single Use, Feeding Tube, Stomach Tube, Suction Catheter, Nelaton Catheter, Sterile Heparin Caps for Single Use, IV. Cannula for Single Use, Three Way Stopcock and Extension Tube, Syringe for Insulin, I.V. Flow Regulator for Single Use, Transfusion Set, Infusion Set with Burette, Scalp Vein Set for Single Use, Sterile Safety Auto Disable Syringes for Single Use, Infusion Connector and Accessory for Single Use, Urine Bags, Sterile Vaginal Dilators for Single Use, Digital Blood Pressure Monitors (Digital Sphygmomanometers), Digital Thermometers, Infra-red Forehead Thermometers, Basic Dressing Pack, First Aid Kits, Disposable Surgical Pack, Surgical Scalpel, Disposable Fistula Needles, Disposable Blood Lines, Disposable Endotracheal Tubes, Disposable Breathing Circuits, Disposable Insulin Pen Needles, Disposable Vacuum Blood Tubes, Medical Examination Gloves, Anesthesia Masks, Non Sterile Ostomy Bag, Disposable Enteral Feeding Sets

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 and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5_003509_0004_Rev_01

Report No.: SH21130601

Valid from: 2021-04-27

Valid until: 2024-04-23

Date, 2021-04-27



Christoph Dicks
Head of Certification/Notified Body

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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): Zibo Gray International Co., Ltd.
No.77 Zhanghuan Road, 255000 Zibo City, Shandong, PEOPLE'S
REPUBLIC OF CHINA

See scope of certificate