



Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



Product Service

Certificate

No. Q6 071213 0034 Rev. 01

Holder of Certificate: **MEDTRUE ENTERPRISE CO., LTD.**

Room No. 301-302
Hongpujiezuo Mansion
186-1 JiangdongZhonglu Road
210019 Nanjing
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Production and Distribution of Medical Dressing, Medical and Surgical Instrument, Disposable Medical Tube/Catheter Sets, Disposable Medical Infusion and Transfusion Sets, Disposable Medical Needle, Medical Glove, Hospital Consumables, Wheelchairs (for detailed information see page 2)**

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). 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:Q6 071213 0034 Rev. 01

Report No.: SH24057001
Valid from: 2024-12-01
Valid until: 2027-11-30

Date, 2024-11-29

Christoph Dicks
Head of Certification/Notified Body



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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):

MEDTRUE ENTERPRISE CO., LTD.

Room No. 301-302, Hongpujiezuo Mansion, 186-1
JiangdongZhonglu Road, 210019 Nanjing, PEOPLE'S REPUBLIC
OF CHINA

See Scope of Certificate

For the product(s)/product category (ies):

Medical Dressing

Product of Zinc Oxide Adhesive Plaster, Alcohol Swab, Absorbent Gauze (Gauze in Roll, Gauze in Zigzag, Guttet Gauze), Medical Elastic Bandage, Gauze Bandages, Gauze Swabs (Sponges), Disposable Medical Face Masks, Plaster of Paris Bandages, Sterile Hemostasis Adhesive Dressing Series (including sterile wound plaster, liquid transfusion plaster and adhesive dressing), Hydrocolloid Dressing, Foam Dressing, Medical Tapes

Medical and Surgical Instrument

Product of Surgical Blade, Surgical Needle with Thread, Sphygmomanometer, Stethoscope

Disposable Medical Tube/Catheter Sets

Product of Foley Catheter, Endotracheal Tube, Stomach Tube, Oxygen Mask, Enteral Feeding Bag Set, Silicone/SEBS/PVC Manual Resuscitators

Disposable Medical Infusion and Transfusion Sets

Product of Disposable Infusion Set, Disposable Transfusion Set, Disposable Syringe, Stopcocks

Disposable Medical Needle

Product of Blood Lancet, Hypodermic Needle

Medical Glove

Product of Latex Glove

Hospital Consumables

Disposable Vaginal Speculum, Disposable Cervical Brushes, Drainage Bag, Ostomy Bag, Plastic Blood Bag for Single Use

Wheelchairs