



Product Service

Certificate

No. Q5 071213 0033 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:

Design and Development,
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,
Anesthesia Machine, Patient Monitors, Electrocardiographs,
Digital Blood Pressure Monitors
(Digital Sphygmomanometers), Digital Thermometers,
Operating Tables, Operation Lamps, Electric Hospital Beds,
Wheelchairs(for detailed information see below)

The Certification Body of TUV SUD 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.: SH1957012

Valid from: 2020-12-03

Valid until: 2022-11-30

Date, 2020-12-03

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): MEDTRUE ENTERPRISE CO., LTD.
Room No. 301-302, Hongpujiezuo Mansion, 186-1
JiangdongZhonglu Road, 210019 Nanjing, PEOPLE'S REPUBLIC
OF CHINA

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

Medical Dressing

Product of Non-Woven Material, Zinc Oxide Adhesive Plaster, Alcohol Swab, Non-woven Wound Care Products, Absorbent Gauze (Gauze in Roll, Gauze in Zigzag, Guttet Gauze), Medical Elastic Bandage, Gauze Bandages, Gauze Swabs (Sponges), Disposable Medical Face Masks, Disposable Medical Caps, Disposable Shoe Covers, Disposable Surgical Gowns, Plaster of Paris Bandages, Sterile Hemostasis Adhesive Dressing Series, (including sterile wound plaster, liquid transfusion plaster and adhesive dressing), Hydrocolloid Dressing, Foam Dressing

Medical and Surgical Instrument

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

Disposable Medical Tube/Catheter Sets

Product of Foley Catheter, Endotracheal Tube, Stomach Tube, Oxygen Mask, Enteral Feeding Bag Set, Laryngeal Mask Airway, Oral Pharyngeal Airway, 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, Vinyl Glove

Hospital Consumables

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

Anesthesia Machine, Patient Monitors, Electrocardiographs

Digital Blood Pressure Monitors (Digital Sphygmomanometers)

Digital Thermometers, Operating Tables, Operation Lamps

Electric Hospital Beds, Wheelchairs