



Product Service

Certificate

No. Q5 087117 0012 Rev. 02

Holder of Certificate: **Weigao Medical International Co., Ltd.**
No.1 Weigao Road
High-tech Industrial Development Zone
264210 Weihai, Shandong Province
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Design and Development, Production and Distribution of Sterile / Non-sterile Non-active Medical Device (For detailed information see following pages).**

Design and Development, Production and Distribution of Negative Pressure Drainage Device, Steam sterilizers.

Production and Distribution of Sterile / Non-sterile Non-active Medical Device (For detailed information see following pages).

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). See also notes overleaf.

Report No.: BJ20094601

Valid from: 2020-04-17

Valid until: 2023-04-16

Date, 2020-02-20

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):

Weigao Medical International Co., Ltd.
No.1 Weigao Road, High-tech Industrial Development Zone, 264210
Weihai, Shandong Province, PEOPLE'S REPUBLIC OF CHINA

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Detailed Information:

Design and Development, Production and Distribution of Sterile Infusion Sets for single use, Sterile Transfusion Sets for single use, Sterile Hypodermic Syringes for single use, Sterile Plastic Blood Bag for single use, Sterile Intravenous Needles for single use, Sterile Blood Collection Needles for single use, Sterile High Pressure Angiographic Syringes for single use, Sterile Retractable Auto-Disable Syringe for single use, I.V.Catheter for single use, Sterile Hypodermic Needles for single use, Retractive Safety I.V. catheter, Haemoconcentrator for single use, Arterial blood line filter, Perfusion tubing set for single use, Single use cardioplegia delivery system, Suction devices for single use, Oocyte Pick-up Needle, IVF Embryo Transfer Catheter, NPWT Dressing Kits, NPWT Dressing, Nasal Tampon, Heart Fixation Device, Urine Bags, Urethral catheter, Tracheostomy Tubes, Insulin Syringe, Fistula Needles, Membrane Oxygenator, Blood Collection Tube For Single Use, Silicone Foley catheters, Tracheal Tubes, Hydrogel Dressing, Hydrocolloid Wound Dressing, Alginate Dressing, Biopsy Needles For Single Use, Insulin needles for single use, safety scalp vein set, Stopcock for Single Use, Disposable Circular Stapler, Disposable Hemorrhoids and Prolapse Stapler Set, Disposable Linear Cutting Stapler, Disposable Linear Stapler, Disposable Trocar, Disposable Cavity Cutting Stapler, Sterile Micro-Filter Syringes for Single Use, Disposable Linear Cutting Stapler Reload, Disposable Linear Stapler Reload, Disposable Cavity Cutting Stapler Reload, Oral/Enteral Syringe for Single Use, Sterile Safety Hypodermic Needle.

Production and Distribution of Sterile Prefilled Syringe composite (without needle) for single use, Sterile Precision Solution Filters for single use, Sterile Infusion Connector without Needles for single use, Sterile Heparin Cap for single use, Sterile Lachrymal Cannula Needle for single use, Feeding Set, Oxygen Masks, sterile blood lancets, Suction Connecting Tube with and without Yankauer, Suction Yankauer, Silicone/SEBS/PVC Manual Resuscitators (Including Mask, Positive End-Expiratory Pressure Valve, Oxygen Tube, Reservoir Bag, Mouth opener, Oropharyn-geal airway, Manometer), Sterile pressure connector tube for Single Use, Inflation device, Sterile Disposable Dressing packs and procedure packs, Surgical Packs Kit, Dialysis Kit / Haemodialysis Fistula ON/OFF Kit, Disposable Medical Tray, Male Circumcision Kit.