



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 087117 0011 Rev. 01

Manufacturer:

Weigao Medical International Co., Ltd.

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

EC-Representative:

MedNet GmbH

Borkstrasse 10, 48163 Muenster, GERMANY

Product Category(ies):

Non-active devices for anaesthesia, emergency and intensive care, Non-active devices for injection, infusion, transfusion and dialysis, Non-active instruments, Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART), Bandages and wound dressings, Suture material and clamps, Active surgical devices.
(for detailed products information see attachment)

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

BJ1894607

Valid from:

2019-04-17

Valid until:

2024-04-16

Date,

2019-01-18

Stefan Preiß



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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

Detailed products information:

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, Ovum Pick-up Needle, IVF Embryo Transfer Catheter, NPWT Dressing Kits, NPWT Dressing, Eye Spear, Nasal Tampon, Stress Incontinence Tampon, Heart Fixation Device, Membrane Oxygenator, Negative Pressure Drainage Device, Urethral catheter, Tracheostomy Tubes, Insulin syringe, fistula needles, sterile blood lancets, Tracheal Tubes, Silicone Foley catheters, Hydrogel Dressing, Hydrocolloid Wound Dressing, Alginate Dressing, Biopsy Needles For Single Use, Suction Connecting Tube with and without Yankauer, Suction Yankauer, 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 and reload, Disposable Linear Stapler and reload, Disposable Trocar, Disposable Cavity Cutting Stapler and reload, Sterile Micro-Filter Syringes for Single Use, Silicone/SEBS/PVC Manual Resuscitators (Including Mask, Positive End-Expiratory Pressure Valve, Oxygen Tube, Reservoir Bag, Mouth opener, Oropharyn-geal airway, Manometer).