

EC Certificate
Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60138811 0001

Report No.: 15065307 008

Manufacturer: GCMEDICA ENTERPRISE LTD.(WUXI)
Loujin Industrial Park, Shuofang
Wuxi
214143 Jiangsu
China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60130545 0001

Expiry Date: 2024-02-07

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2019-05-24

Date: 2019-05-24



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: DD 60138811 0001
Report No.: 15065307 008

Manufacturer: GCMEDICA ENTERPRISE LTD.(WUXI)
Loujin Industrial Park, Shuofang
Wuxi
214143 Jiangsu
China

Products:

Closed Suction Catheters, Infusion Sets / Infusion Sets with Burette, Transfusion Sets / Transfusion Sets with Burette, Extension Tubes with 3 Way Stopcock, Heparin Caps, Frazier Suction Tubes, Mini Sucker, Suction Connecting Tubes with and without Yankauer, Nasal Oxygen Cannula, Oxygen Masks, Non-Rebreath Masks, Aerosol Masks with Nebulizer, Multi-vent Masks/Venturi Masks, Tracheostomy Masks, Air Cushion Face Masks, Suction Catheters, Stomach Tubes and Feeding Tubes, Endotracheal Tubes / Reinforced Endotracheal Tubes, Tracheotomy Tubes, Oxygen Humidifiers, Breathing Circuits, HMEF(Heat and Moisture Exchanger Filters), HME(Heat and Moisture Exchanger), Bacterial/Viral Filters for Breathing or Anesthesia Circuit, Endoscopic Suction and Irrigation Sets, Veress Needles, Laryngeal Masks, Uterine Aspiration Curettes / Uterine Aspiration Tubes, Insufflator Tubings, Suction Specimen Traps, Yankauer Handles, Poole Yankauer, Capnography Masks, Capnography Nasal Cannulas, Irrigation Pump Tubings;

Date: 2019-05-24

Notified Body



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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Aspects of manufacture concerned with securing and maintaining sterile conditions:

Magnetic Drapes for Metal Surgical Device Collection,
Suture Retrievers, Decanting Devices/Mixing Cannulas,
Spigots Catheters, Stoppers, Flashing Bags for cleaning
purpose (Sitz Bath Bags), Enema Bags, Urine Meters, Urine
Bags, Oropharyngeal Airways, Nasopharyngeal Airways,
Surgical Brushes, Vaginal Speculums, Nelaton Catheters,
Irrigating Syringes, Ear/Ulcer Syringes,
Mucosal Atomization Devices, TUR/Bladder
Irrigation Sets, Arthroscopy Irrigation Sets, Vessel
Cannula, Bowel Irrigation Systems, Disposable Camera
Covers/Light Handle Covers, Basin Drapes, Rinsing
Devices/Blower Devices, Apron/Drapes, Adaptors/Connectors,
Floor Suction Devices, Male Catheter Condoms, Rectal
Urodynamic Balloon Catheters, External Catheters,
Waste Collection Bags, Scleral Markers, Endoscope Camera
Sleeves, Needle Counters, Stylets, Drainage Tubes,
Dental Irrigation Sets, ENT-single use suction tubes

Date: 2019-05-24

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