Certificate

Quality Management System
EN ISO 13485:2016
EN ISO 13485:2016/AC:2018
EN ISO 13485:2016/A11:2021

Registration No.:	SX 2082446-1
Certificate Holder:	GCMEDICA ENTERPRISE LTD.(WUXI) Loujin Industrial Park, Shuofang, Wuxi, 214143 Jiangsu P.R. China
Scope:	Design and Development, Manufacture and Distribution of Yankauer Handles, Poole Yankauer, Rinsing Devices / Blower Devices, Uterine Aspiration Curettes / Uterine Aspiration Tubes, Adaptors / Connectors, Decanting Devices / Mixing Cannulas, Magnetic Drapes for Metal Surgical Device Collection, Suction Connecting Tubes with and without Yankauer, TUR / Bladder Irrigation Sets, Transfusion Sets / Transfusion Sets with Burette, Extension Tubes with 3 way Stopcock, Endoscopic Suction and Irrigation Sets, Disposable Camera Covers / Light Handle Covers, Scleral Markers, Vacuum Drainage Bottles, Closed Suction Catheters, Infusion Sets / Infusion Sets with Burette, Heparin Caps, Frazier Suction Tubes, Mini Sucker, Nasal Oxygen Cannula, Oxygen Masks, Non-Rebreath Masks, Aerosol Masks with Nebulizer, Multi-vent Masks / Venturi Masks, Tracheostomy Masks, Air Cushion Face Masks, Suction Catheter, Stomach Tubes and Feeding Tubes, Endotracheal Tubes / Reinforced Endotracheal Tubes, Tracheostomy Tubes, Oxygen Humidifiers, Breathing Circuits, HMEF(Heat and Moisture Exchanger Filters), HME(Heat and Moisture Exchanger),

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.:	326059265-200
Effective date:	2025-05-07
Expiry date:	2028-04-23
Issue date:	2025-05-07

Replaces certificate SX 2082446-1 issued 2024-03-26

This certificate can be validated on https://www.certipedia.com

Herbert Zhong
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

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Wuxi, 214143 Jiangsu
P.R. China

Bacterial / Viral Filters for Breathing or Anesthesia Circuit, Suture Retrievers, 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, Arthroscopy Irrigation Sets, Vessel Cannula, Pressure Infusion Bags, Emesis Bags and Dispensers, Suction Specimen Drain Bags, Spirometers, Bowel Irrigation Systems, Veress Needles, Laryngeal Masks, Basin Drapes, Apron / Drapes, Floor Suction Devices, Male Catheter Condoms, Rectal Urodynamic Balloon Catheters, External Catheters, Urine Specimen Containers, Medicine Cups, Manual Resuscitators, Insufflator Tubings, Waste Collection Bags, Suction Specimen Traps, Fecal Collection Devices, Endoscope Camera Sleeves, Needle Counters, Capnography Masks, Capnography Nasal Cannulas, Suction liners / Suction Canisters, Dental Irrigation Sets, Irrigation Pump Tubing, ENT-Single Use Suction Tubes, Stylets, Light Handles, Drainage Tubes, Medical Sponges, Air Flow Blankets, Powered Patient Transfer Systems, Pump For Inflatable Patient Transfer Sliding Mattresses, Inflatable Patient Transfer Sliding Mattresses, Urine Absorbing System For Incontinence, Medicine Chamber Spacers, Gastric Lavage Kits, Intrauterine Coil Removal Hooks, Polyp Traps;
Provision of Ethylene Oxide Sterilization Service for Single-use Medical Devices in accordance with EN ISO 11135:2014

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The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o GCMEDICA ENTERPRISE LTD.(WUXI) Loujin Industrial Park, Shuofang, Wuxi, 214143 Jiangsu P.R. China	Design and Development, Manufacture and Distribution of Yankauer Handles, Poole Yankauer, Rinsing Devices / Blower Devices, Uterine Aspiration Curettes / Uterine Aspiration Tubes, Adaptors / Connectors, Decanting Devices / Mixing Cannulas, Magnetic Drapes for Metal Surgical Device Collection, Suction Connecting Tubes with and without Yankauer, TUR / Bladder Irrigation Sets, Transfusion Sets / Transfusion Sets with Burette, Extension Tubes with 3 way Stopcock, Endoscopic Suction and Irrigation Sets, Disposable Camera Covers / Light Handle Covers, Scleral Markers, Vacuum Drainage Bottles, Closed Suction Catheters, Infusion Sets / Infusion Sets with Burette, Heparin Caps, Frazier Suction Tubes, Mini Sucker, Nasal Oxygen Cannula, Oxygen Masks, Non-Rebreath Masks, Aerosol Masks with Nebulizer, Multi-vent Masks / Venturi Masks, Tracheostomy Masks, Air Cushion Face Masks, Suction Catheter, Stomach Tubes and Feeding Tubes, Endotracheal Tubes / Reinforced Endotracheal Tubes, Tracheostomy Tubes, Oxygen Humidifiers, Breathing Circuits, HMEF(Heat and Moisture Exchanger Filters), HME(Heat and Moisture Exchanger), Bacterial / Viral Filters for Breathing or Anesthesia Circuit, Suture Retrievers, 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, Arthroscopy Irrigation Sets, Vessel Cannula, Pressure Infusion Bags, Emesis Bags and Dispensers, Suction Specimen Drain Bags, Spirometers, Bowel Irrigation Systems, Veress Needles, Laryngeal Masks, Basin Drapes, Apron / Drapes, Floor Suction Devices, Male Catheter Condoms, Rectal Urodynamic Balloon Catheters, External Catheters, Urine Specimen Containers, Medicine Cups, Manual Resuscitators, Insufflator Tubings, Waste Collection Bags, Suction Specimen Traps, Fecal Collection Devices, Endoscope Camera Sleeves, Needle Counters, Capnography Masks, Capnography Nasal Cannulas, Suction liners / Suction Canisters, Dental Irrigation Sets, Irrigation Pump Tubing, ENT-Single Use Suction Tubes, Stylets, Light Handles, Drainage Tubes, Medical Sponges; Provision of Ethylene Oxide Sterilization Service for Single-use Medical Devices in accordance with EN ISO 11135:2014

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