

A1 / 07.17



# EC Certificate

## **Production Quality Assurance System**

Directive 93/42/EEC on Medical Devices (MDD), Annex V (Devices in Class IIa, IIb or III)

No. G2 18 01 73283 041

Manufacturer: Ningbo Greetmed Medical

Instruments Co., Ltd.

18F-3, No.1 Building

Wante Business Centre, Hi-Tech Zone

315042 Ningbo

PEOPLE'S REPUBLIC OF CHINA



**EC-Representative:** Shanghai International Holding

Corp. GmbH (Europe)

Eiffestraße 80 20537 Hamburg **GERMANY** 

**Non-active Medical Devices Product** 

(For detailed information please see Category(ies):

attachment)

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

Report No.: SH1829914

2018-03-29 Valid from: 2021-04-17 Valid until:



Date, 2018-03-29

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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No. G2 18 01 73283 041

Facility(ies):

Ningbo Greetmed Medical Instruments Co., Ltd. 18F-3, No.1 Building, Wante Business Centre, Hi-Tech Zone, 315042 Ningbo, PEOPLE'S

REPUBLIC OF CHINA

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### Supplement 001 dated 2018-03-29

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

Tracheal Tubes, Surgical Gloves,

Electronic Sphygmomanometers, Digital Thermometers,

Infra-red Ear Thermometers, Infra-red Forehead Thermometers,

Disposable Infusion Sets, Disposable Syringe Sets,

Disposable Blood Transfusion Sets,

Disposable Scalp Vein Sets, Oxygen Masks, Aerosol Masks,

Nasal Oxygen Cannula, Non-Rebreath Masks,

Disposable Surgical Blades, Sterile Blood Lancets,

Suction Catheters, Feeding Tubes, Stomach Tubes,

Connecting Tubes with Yankauer Handle, Nelaton Catheters,

Reinforced Endotracheal Tubes, Laryngeal Mask,

Mucus Extractor, Wound Drainage Reservoir,

Three-way Stopcocks, Heparin Caps, I.V. Cannula,

Insulin Syringe, Infusion Set with Burette,

Hypodermic Needle, Closed Suction Catheter,

Safety Syringes, CPR Masks,

Venturi Masks, Ultrasonic Nebulizer,

Compressor Nebulizer, Tracheostomy Mask,

Manual Resuscitators,

Latex Foley Catheter, T-Drainage Tube,

Penrose Tube, Lap Sponges, Insulin Pen Needles,

Electrocardiograph, Transcutaneous Jaundice Detector,

Neonate Bilirubin Phototherapy Equipment,

Lubricating Jelly, Urethral Catheters,

Endotracheal Tube Introducers, Anesthetic Breathing Circuits,

Endotracheal Tubes with Evacuation Lumen,

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O2+CO2 Sampling Cannulas, Humidifier Jar, Mask Nebulizer Container, Auto-disable Syringe, Anesthesia Mask, Resuscitation Mask, Nebulizers with Mouth-pieces, Oxygen Connection Tubings, Nebulizer Set, Three-way Stopcock and Extension Tube, Dental Needles, Disposable Vacuum Blood Collection System, Disposable Umbilical Cord Scissors, Blood-Collecting Needles, Disposable Anesthesia Laryngoscope, Heat & Moisture Exchanger Filters, Breathing System Filters, Drainage Tubes, Screw Cap, Combi Stopper, Enema Set

Munich, CRT, 2018-03-29

Stefan Preiß

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Certification Medical Technology

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