



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

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

No. G2 095166 0015 Rev. 02

Manufacturer:

**NINGBO TRUSTLAB
INSTRUMENTS CO., LTD**

18-7, No.1 Building, Wante Business Centre
Hi-tech zone
315042 Ningbo
PEOPLE'S REPUBLIC OF CHINA

**Product
Category(ies):**

-Non-active devices for anaesthesia, emergency and
intensive care
-Non-active devices for injection, infusion, transfusion
and dialysis
-Non-active instruments
-Bandages and wound dressings
-Monitoring devices of vital physiological parameters
-Medical Gloves
(For detailed information please see 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.:

SH191044EXT01

Valid from:

2020-03-06

Valid until:

2024-05-26

Date,

2020-03-06

Christoph Dicks
Head of Certification/Notified Body



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[Non-active devices for anaesthesia, emergency and intensive care]
Oxygen Masks, Venturi Masks, Nebulizer Masks. Non-Rebreath Masks, Tracheostomy Masks, Nebulizers with Mouth-pieces, CPR Masks, Anesthesia Mask, Resuscitation Mask, Nasal Oxygen Cannula, Oxygen Connection Tubings, Nebulizer Set, Reinforced Endotracheal Tubes, Urethral Catheters, Tracheal Tubes, Nelaton Catheters, Connecting Tubes with Yankauer Handle, Laryngeal Masks, Suction Catheters, Feeding Tubes, Stomach Tubes, Manual Resuscitators, Anesthetic Breathing Circuits, Dental Needles, Scalp Vein Set, I.V. Cannula, Hypodermic Needle, Wound Drainage Reservoir, Breathing System Filters, Heat & Moisture Exchanger Filters, Drainage Tubes, Humidifier Bottle, Mask Nebulizer Container, Mucus Extractor, Closed Suction Catheter, T-Drainage Tube, Penrose Tube, Endotracheal Tube Introducers, Endotracheal Tubes with Evacuation Lumen, O2+CO2 Sampling Cannulas, Insulin Pen Needles, Screw Cap, Combi Stopper, Enema Set, Lubricating Jelly

[Non-active devices for injection, infusion, transfusion and dialysis]
Disposable Infusion Sets, Disposable Syringes, Three-way Stopcocks, Heparin Caps, Infusion Set with Burette, Disposable Blood Transfusion Set, Three Way Stopcock and Extension Tube, Insulin Syringe, Disposable Vacuum Blood Collection System, Auto-disable Syringe, Safety Syringes

[Non-active instruments]
Disposable Surgical Blade, Blood-Collecting Needles, Disposable Umbilical Cord Scissors, Sterile Blood Lancets

[Bandages and wound dressings]
Lap Sponges

[Monitoring devices of vital physiological parameters]
Electronic Sphygmomanometers, Digital Thermometers, Infra-red Ear Thermometers, Infra-red Forehead Thermometers

[Medical Gloves]
Surgical Gloves