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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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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

[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



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Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V

(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 095166 0017 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):

**-General non-active, non-implantable medical
devices**

**-Non-active devices for anaesthesia, emergency
and intensive care**

-Bandages and wound dressings

(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 in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.:

SH191044EXT01

Valid from:

2020-03-06

Valid until:

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Date,

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Christoph Dicks

Head of Certification/Notified Body



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Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V

(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 095166 0017 Rev. 02

[General non-active, non-implantable medical devices]

Surgical Gowns, Isolation Gowns, Non-woven Face Masks, Wooden Tongue Depressors, Surgical Drapes

[Non-active devices for anaesthesia, emergency and intensive care]

Rectal Tubes, Oropharyngeal Airways, Nasopharyngeal Airways, External Male Catheter, Irrigation Syringes, Umbilical Cord Clamp, Urine Bag, Disposable Vaginal Speculum, Male Swab, Female Swab, Transportation Swabs with Medium, Disposable Anoscope, Sterile Vaginal Applicator, Sterile Urine Containers, Medicine Cup, Wooden Ayre Spatulas, Disposable Infusion Connection Tube, Sterile Examination Gloves, First-Aid-Kit, Disposable Plastic Forceps, Surgical Set, Surgical Brush, Disposable Colostomy Bags, Urine Bag Infant, Enema Bag, I.D. Bracelets, Spigot, Disposable Anesthesia Laryngoscope, Nasal Speculas, Gynecological Sets, Cervical Brushes

[Bandages and wound dressings]

Elastic Bandage, Gauze Swabs, Gauze Bandages, Gauze Balls, Absorbent Cotton, Cotton Tip Applicators, Non-woven Sponge, Alcohol Swabsticks, Alcohol Prep Pad, Gauze Roll, Eye Pad, Sterile Hemostasis Adhesive Dressing Series (Sterile Wound Plaster, Liquid Transfusion Plaster and Adhesive Dressing), Absorbent Cotton Balls, Non-woven Balls, Dressing Kits



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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 095166 0013 Rev. 01

Manufacturer:

**NINGBO TRUSTLAB
INSTRUMENTS CO., LTD**

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

Facility(ies):

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): Urethral Catheters, All Silicone Foley
Catheters, Tracheostomy Tubes, Condom,
Electrosurgical Pencils, Blood Bags, Sterile
Hydrocolloid Dressings, Non-absorbable
Surgery Suture**

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.:

SH19104404

Valid from:

2019-07-15

Valid until:

2021-07-20

Date,

2019-07-15

Stefan Preiß

Head of Certification/Notified Body



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Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex V
(Devices in class I with measuring function)

No. G2M 095166 0016 Rev. 00

Manufacturer:

NINGBO TRUSTLAB

INSTRUMENTS CO., LTD

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

Facility(ies):

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):

**Aneroid Sphygmomanometers,
Mercury Free Clinical Thermometer**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for the manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with the metrological requirements of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.:

SH18104403

Valid from:

2018-10-16

Valid until:

2021-07-24

Date,

2018-10-16

Stefan Preiß



Product Service

Certificate

No. Q5 095166 0012 Rev. 01

Holder of Certificate: **NINGBO TRUSTLAB
INSTRUMENTS CO., LTD**
18-7, No.1 Building, Wante Business Centre
Hi-tech zone
315042 Ningbo
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Design, Development, Production and
Distribution of Medical Device**
(For detail information see attachment)

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH19104404

Valid from: 2019-07-21

Valid until: 2022-07-20

Date, 2019-07-15

Stefan Preiß
Head of Certification/Notified Body

Certificate

No. Q5 095166 0012 Rev. 01

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies): NINGBO TRUSTLAB INSTRUMENTS CO., LTD
18-7, No.1 Building, Wante Business Centre, Hi-tech
zone, 315042 Ningbo, PEOPLE'S REPUBLIC OF
CHINA

Certificate

No. Q5 095166 0012 Rev. 01

Design, Development, Production and Distribution of Urethral Catheters, All Silicone Foley Catheters, Tracheostomy Tubes, Condom, Electrosurgical Pencils, Blood Bags, Sterile Hydrocolloid Dressings, Non-absorbable Surgery Suture.

Production and Distribution of 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, Disposable Infusion Sets, Disposable Syringes, Three-way Stopcocks, Heparin Caps, Dental Needles, Scalp Vein Set, I.V. Cannula, Hypodermic Needle, Infusion Set with Burette, Disposable Blood Transfusion Set, Three Way Stopcock and Extension Tube, Insulin Syringe, Wound Drainage Reservoir, Surgical Gloves, Disposable Surgical Blade, Blood-Collecting Needles, Disposable Vacuum Blood Collection System, Disposable Umbilical Cord Scissors, Rectal Tubes, Oropharyngeal Airways, Nasopharyngeal Airways, External Male Catheter, Irrigation Syringes, Elastic Bandage, Gauze Swabs, Gauze Bandages, Gauze Balls, Lap Sponges, Absorbent Cotton, Cotton Tip Applicators, Non-woven Sponge, Alcohol Swabsticks, Alcohol Prep Pad, Umbilical Cord Clamp, Urine Bag, Wooden Tongue Depressors, Surgical Gowns, Isolation Gowns, Non-woven Face Masks, Cervical Brushes, Disposable Plastic Forceps, Disposable Vaginal Speculum, Male Swab, Female Swab, Transportation Swabs with Medium, Disposable Anoscope, Sterile Vaginal Applicator, Sterile Urine Containers, Aneroid Sphygmomanometers, Spirometer, Electrode Code, Ultrasound Gel, Zinc Oxide Adhesive Plaster, PE Tape, Silk Tape, Non-woven Tape, Self-adhesive Bandage, Medicine Cup, Wooden Ayre Spatulas, Disposable Infusion Connection Tube, Gauze Roll, Eye Pad, Sterile Examination Gloves, Breathing System Filters, Heat & Moisture Exchanger Filters, Drainage Tubes, Humidifier Bottle, Mask Nebulizer Container, Auto-disable Syringe, Oxygen Concentrator, Electric Suction Apparatus, First-Aid-Kit, Sterile Hemostasis Adhesive Dressing Series (Sterile Wound Plaster, Liquid Transfusion Plaster and Adhesive Dressing), Absorbent Cotton Balls, Dressing Kits, Surgical Brush, Surgical Drapes, Surgical Set, Gynecological Sets, Disposable Colostomy Bags, Urine Bag Infant, Enema Bag, I.D. Bracelets, Spigot, Disposable Anesthesia Laryngoscope, Nasal

Certificate

No. Q5 095166 0012 Rev. 01

Speculas, Mercury Free Clinical Thermometer, Mucus Extractor, Closed Suction Catheter, T-Drainage Tube, Penrose Tube, Endotracheal Tube Introducers, Endotracheal Tubes with Evacuation Lumen, O2+CO2 Sampling Cannulas, Safety Syringes, Sterile Blood Lancets, Insulin Pen Needles, Screw Cap, Combi Stopper, Enema Set, Lubricating Jelly, Non-woven Balls, Electronic Sphygmomanometers, Digital Thermometers, Infra-red Ear Thermometers, Infra-red Forehead Thermometers.