



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 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:

2024-05-26

Date,

2020-03-06

Christoph Dicks

Head of Certification/Notified Body



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[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