DAkkS
Deutsche
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D-ZM-11321-01-00

Product Service

Certificate

No. Q5 093011 0009 Rev. 00

Digitally signed by Granaci Boris
Date: 2021.07.08 12:48:11 EEST
Reason: MoldSign Signature
Location: Moldova

Holder of Certificate: **Ningbo Foyomed Medical Instruments Co., Ltd.**
Room 805-806
No. 299 of Jiangnan Yipin Garden
Hi-Tech Zone
315040 Ningbo
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of Medical Devices (for detailed 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.: SH1899404

Valid from: 2019-03-25
Valid until: 2022-01-26

Date, 2019-03-25

Stefan Preiß

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 093011 0009 Rev. 00

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 Foyomed Medical Instruments Co., Ltd.
Room 805-806, No. 299 of Jiangnan Yipin Garden,
Hi-Tech Zone, 315040 Ningbo, PEOPLE'S
REPUBLIC OF CHINA**

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

Design, Development, Production and Distribution of Silicone Urethral Catheters, Tracheostomy Tubes for Single Use, Non-absorbable Surgical Sutures with/without Needles, Condom

Production and Distribution of Endotracheal Tube, Reinforced Endotracheal Tube, Latex Foley Catheter, Urethral Catheters (PVC), Nelaton Catheters(latex), Sterile Feeding Tubes, Disposable Rectal Tubes, Sterile Suction Catheters, Disposable Stomach Tubes, Disposable Mucus Extractors, Disposable Umbilical Cord Clamps, Disposable I.D. Bracelets, Laryngeal Masks Airways, Tracheostomy Masks, Oxygen Masks, Nebulizers Masks, Venturi Masks, Oxygen Masks with Reservoir Bag, Connecting Tubes with Yankauer Handle ,Oxygen Connection Tubings, Nasal Oxygen Cannula, Safety Syringes, Auto Disable Syringes, Disposable Syringe, Disposable Hypodermic Needles, Safety Disable Syringes, Sterile Infusion Sets for Single Use, Sterile Transfusion Sets for Single Use, Sterile Scalp Vein Type Needles for Single Use, Disposable Irrigating and Feeding Syringes, Three-way Stopcocks(with Extension Tube), Heparin Caps, I.V. Cannula for Single Use, Insulin Needles for Single Use, Disposable Scalpel with Plastic Handle, Blood Lancet, Sterile Surgical Blade, Gauze Rolls, Gauze Bandages, Gauze Sponges, Alcohol Pad, CPR Mask, Gauze Balls, Non-woven Balls(with X-ray), Lap Sponges, Cotton Tipped Applicators, Absorbent Cotton Balls, Medical Dressing Kits, Dressing Eye

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Pads, Absorbent Cotton Wools, Surgical Brushes, Oropharyngeal Airway, Resuscitation Mask, Silicone/SEBS/PVC Manual Resuscitators, Wound Drainage Reservoir, Urine Bag, Swab, Disposable Cervical Brushes, Sterile Examination Gloves, Sterile Latex Surgical Gloves, Surgical Gowns, Digital Thermometers, Digital Blood Pressure Monitors, Electronic Sphygmomanometers, Medical Bandages, Adhesive Dressing Series, Non-woven Gowns, Non-woven Face Mask, Non-woven Caps, Non-woven Shoe Cover, PE Aprons, Stethoscope, ECG Electrode, TENS Electrode, Wheel Chairs, Walking Aids, Operating Tables, Operating Lamps, Oxygen Concentrators, Vaginal Speculum, Disposable Surgical Drape, Adult Diaper, Silicone Condom Catheter, Wooden Tongue Depressors, Frozen Ice Pack, Mattresses, Ear/Ulcer Syringe, Single-use Medical Packing for Sterilized Medical Devices

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