DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q6 093011 0010 Rev. 00

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 tuvsud.com/ps-cert

Scope of Certificate: **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 (excluding subclause 7.3), which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q6 093011 0010 Rev. 00

Report No.: SH2199401

Valid from: 2022-07-06
Valid until: 2025-01-26

Date, 2022-07-06

Christoph Dicks
Head of Certification/Notified Body

TÜV®

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q6 093011 0010 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

See Scope of Certificate

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

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 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

TÜV®

Add value.
Inspire trust.

TÜV SÜD Product Service GmbH· Ridlerstr. 65 · 80339 Munich · Germany

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

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
93011	GCN-SH24994A01	medical_devices@tuvsud.com		2024-06-20	1 of 4

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 093011 0011 Rev. 00

Reference: GCN-SH24994A01

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the above stated manufacturer with the following SRN Number:

SRN Number: CN-MF-000032266

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below.

- Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.
- Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

If devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that

- the manufacturer signed the written agreement under MDR by the date of MDD/ AIMDD certificate expiry;
  or
- provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively.

The transition timelines in accordance Article 120 (3) of MDR that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120 (3c) of MDR, are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition, measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

We reserve the right to invoice any issuance, copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see http://www.tuvsud.com/ps-cert?q=cert:CL 093011 0011 Rev. 00

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-06-20

TÜV SÜD Product Service GmbH
Medical and Health Services

Shengliang Zhou
Shengliang Zhou (Jun 21, 2024 08:59 GMT+8)

Mr. Shengliang Zhou
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

i.A. Clara Höhneke

Clara Höhneke
Application Reviewer

Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device 1 **Disposable Hypodermic Needles** **(Basic UDI-DI:** 697720605NeedleC8)	☒ Class IIa	☒ N/A The product has not changed, only the model description has been adjusted. The model specifications of the product under MDR are differentiated according to the size of the product.	☒ Certification as follows: G2 093011 0006 Rev. 01; NB#0123
Device 2 **Disposable Syringes** **(Basic UDI-DI:** 697720605SyringeF9)	☒ Class IIa	☒ N/A The product has not changed, only the model description has been adjusted. The model specifications of the product under MDR are differentiated according to the size of the product.	☒ Certification as follows: G2 093011 0006 Rev. 01; NB#0123
Device 3 **Disposable Syringes (without needle)** **(Basic UDI-DI:** 697720605Syringe0192)	☒ Class I devices in sterile condition	☒ N/A The Classification was IIa under MDD, Is under MDR. The product has not changed, only the model description has been adjusted. The model specifications of the product under MDR are differentiated according to the size of the product.	☒ Certification as follows: G2 093011 0006 Rev. 01; NB#0123
Device 4 **Sterile Infusion Sets for Single Use** **(Basic UDI-DI:** 697720605Infusion2R)	☒ Class IIa	☒ N/A The product has not changed, only the model description has been adjusted. The model specifications of the product under MDR are differentiated according to the size of the product.	☒ Certification as follows: G2 093011 0006 Rev. 01; NB#0123
Device 5 **Sterile Infusion Sets for Single Use (without needle)** **(Basic UDI-DI:** 697720605Infusion01BF)	☒ Class I devices in sterile condition	☒ N/A The Classification was IIa under MDD, Is under MDR. The product has not changed, only the model description has been adjusted. The model specifications of the product under MDR are differentiated according to the size of the product.	☒ Certification as follows: G2 093011 0006 Rev. 01; NB#0123

Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Not applicable	☒ N/A	☒ N/A	☒ N/A

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-06-20	GCN-SH24994A01	Initial issue