



# Certificate

No. Q5 036336 0056 Rev. 03

**Holder of Certificate:** **Zhejiang Kindly Medical Devices Co., Ltd.**  
No.758, 5th Binhai Road  
Binhai Industrial Park, Longwan District  
325025 Wenzhou, Zhejiang Province  
PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**



**Scope of Certificate:** **Design, Development, Production, Sales and Distribution of Sterile Non-active 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). 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:Q5 036336 0056 Rev. 03](http://www.tuvsud.com/ps-cert?q=cert:Q5 036336 0056 Rev. 03)

**Report No.:** BJ23081201

**Valid from:** 2023-11-01

**Valid until:** 2026-10-31

**Date,** 2023-10-16

Christoph Dicks  
Head of Certification/Notified Body

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**Applied Standard(s):** ISO 13485:2016  
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)  
Medical devices - Quality management systems -  
Requirements for regulatory purposes

**Facility(ies):** **Zhejiang Kindly Medical Devices Co., Ltd.**  
No.758, 5th Binhai Road, Binhai Industrial Park, Longwan District,  
325025 Wenzhou, Zhejiang Province, PEOPLE'S REPUBLIC OF  
CHINA

See Scope of Certificate

## Attachment:

Hypodermic Syringe Needles (Sterile Disposable Needles), Butterfly Needles (Sterile Scalp Vein Sets), Infusion and Irrigation Syringes (Sterile Syringes), Infusion Sets (Sterile Infusion Sets), Administration Sets (Sterile Transfusion Sets), Infusion and Irrigation Syringes (Sterile Burette-Type Infusion Sets), Needles for Collection Under Vacuum (Sterile Blood-Collecting Needles), Carpule Needles (Sterile Dental Needles), Spinal and Epidural Anaesthesia Needles (Sterile Anaesthesia Needles), Stopcocks (Sterile Stopcock), Caps without Needle (Sterile Heparin Cap/Stopper), Extensions (Sterile Extension Sets), Needles for Implantable Systems (Sterile Huber Needles), Arteriovenous Fistula (Sterile Fistula Needles), Dental Mirrors and Handles (Sterile Dental Odontotomaculum and Odontoscope), Blood Collection Tubes (Sterile Disposable Vacuum Venous Blood Specimen Collection Containers), Infusion Sets (Sterile Infusion Sets for Single Use), Caps (Sterile Dual-purposed Connector for Single Use), Caps without Needle (Sterile Injection Site for Single Use), Needles for Infusion and Collection (Sterile Drip Chamber for Single Use), Needles for Infusion and Collection (Sterile Piercing Device for Single Use), Infusion and Irrigation Syringes (Sterile Syringes for Single Use), Cannulas and Tips for Aspiration and Irrigation (Sterile Irrigation Needles for Single Use), Peripheral I.V. Catheters (Sterile I.V. catheter for single use), Hypodermic Pen Needles (Sterile Disposable Insulin Pen Needle), Cardiovascular Introducer Sheaths (Sterile Intravascular Catheter Introducer for Single Use), Biopsy Needles (Sterile Biopsy Needles for Single Use), Intraosseous Infusion and Vertebroplasty Infusion Needles (Sterile Percutaneous Vertebroplasty Kit for Single Use), Blunt Needles (Sterile Dispensing Needles for Single Use), Hypodermic Syringe Needles with Safety Systems (Sterile Safety Needles), Butterfly Needles with Safety Systems (Sterile Safety Scalp Vein Sets), Needles for Collection Under Vacuum with Safety Systems (Sterile Safety Blood-Collecting Needles), Peripheral I.V. Catheters with Safety Systems (Sterile Safety I.V. Catheter for Single Use), Arteriovenous Fistula (Sterile Safety Fistula Needles), Needles for Infusion and Collection (Sterile Luer Adapter), Venous Blood Collection Devices (Sterile Safety Blood Lancet), Venous Blood Collection Devices (Sterile Blood Collection Assembly), Irrigation Disposable Syringes (Sterile Irrigation Syringes), Insulin Syringes (Sterile Syringes for Insulin for Single Use), Disinfection Instruments (Sterile Disinfecting Cap for Single Use), Holders for Collection Needles (Blood Collection Sampling Holder).