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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter I

Certificate No. G15 036336 0061 Rev. 00

Manufacturer:

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

SRN Manufacturer - CN-MF-000007594

Authorized Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

The quality management system has been evaluated in accordance with Regulation (EU) 2017/745, Annex IX Chapter I with a positive result.

Details on devices covered by the quality management system are described on the following page(s). The report referenced below summarises the results of the assessment and includes reference to relevant CS, harmonised standards and test reports.
The certified quality management system is subject to periodical surveillance.

If class I devices in sterile conditions, with measuring function, or reusable surgical instruments are covered by this certificate, the audit was limited to the respective aspects relating to
- establishing, securing, and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

If class IIa or class IIb devices are covered by this certificate, the quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis. The periodical surveillance includes further assessment of the technical documentation on the basis of representative samples.
If class III or class IIb implantable devices are covered by this certificate, an EU Technical Documentation Assessment Certificate in accordance with Annex IX Chapter II is required before placing them on the market.

All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G15 036336 0061 Rev. 00

Report No.: BJ25081204
Preceding Certificate No.: G10 036336 0058 Rev. 02

Valid from: 2026-04-15
Valid until: 2031-04-14

Issue date: 2026-02-24

Christoph Dicks
Head of Certification/Notified Body

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Classification:	Class IIa
Device Group:	MDN 1201 - Non-active non-implantable devices for anaesthesia, emergency and intensive care
Classification:	Class IIa
Device Group:	MDN 1211 - Non-active non-implantable devices for disinfecting, cleaning and rinsing
Classification:	Class IIb
Device Group:	C010101 - PERIPHERAL I.V. CATHETERS
Intended Purpose:	Sterile I.V. Catheter for Single Use is intended for medication infusion when assembled with appropriate matching medical devices such as disposable syringe, infusion set or pressure infusion device.
Classification:	Class IIb
Device Group:	A010102 - BUTTERFLY NEEDLES
Intended Purpose:	Scalp vein sets is intended to be used with disposable syringe, infusion set for intravenous medication infusion.
The validity of this certificate depends on conditions and/or is limited to the following:	-none-

Revision History:

Rev.	Dated	Report	Description
00	2026-04-15	BJ25081204	Renewal of certificate

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