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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

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 036336 0054 Rev. 03

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

Product Category(ies):

Disposable Needles, Scalp Vein Sets, Blood-Collecting Needles, Huber Needles, Fistula Needles, Anaesthesia Needles, Dental Needles for Single Use, Sterile I.V. catheter for single use, Disposable Insulin Pen Needle, Sterile Biopsy Needles for single use, Sterile Percutaneous Vertebroplasty Kit for single use, Sterile Irrigation Needles for Single Use, Safety Needles,Safety Scalp Vein Sets, Safety Blood-Collecting Needles, Safety I.V. Catheter for Single Use, Safety Fistula Needles, Luer Adapter, Safety Blood Lancet, Syringes, Infusion Sets, Transfusion Sets, Burette-Type Infusion Sets, Sterile Intravascular Catheter Introducer for Single Use, Sterile Syringes for Insulin for Single Use, Sterile Disinfecting Cap for Single Use.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II.
This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. 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:G1 036336 0054 Rev. 03

Report No.: BJ20081201

Valid from: 2020-10-27
Valid until: 2024-05-26

Date, 2020-10-27

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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

Add value.
Inspire trust.

TÜV SÜD Product Service GmbH· · Germany

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

Your reference/letter of	Our reference	Email	Fax extension	Date	Page
36336	713235166 | 713268932 | 713253667 | 713342840 | 713341569	medical_devices@tuvsud.com	-	2024-08-23	1 of 10

TÜV SÜD Product Service GmbH
Confirmation Letter

CL 036336 0060 Rev. 02

Reference: 713235166 | 713268932 | 713253667 | 713342840 | 713341569

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-000007594

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)

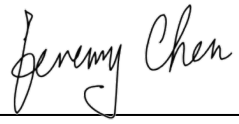
We reserve the right to invoice any issuance, copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see www.tuvsud.com/ps-cert?q=CL 036336 0060

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-08-23

TÜV SÜD Product Service GmbH
Medical and Health Services



Jinglin Chen
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Franziska Eckert
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
Disposable Anaesthesia Needle Basic UDI-DI for all variants: Spinal Needles (AN-S I) **6923033420210030070 14U** Spinal Needles (AN-S II) **6923033420210030070 24W** Epidural Needles (AN-E) **6923033420210030070 34Y** Combined Anaesthesia Needles (AN-S/S I) **6923033420210030070452** Combined Anaesthesia Needles (AN-S/S II) **6923033420210030070554** Combined Anaesthesia Needles (AN-E/S II) **6923033420210030070656**	☒ Class III	☒ N/A	☒ Certification as follows: Certificate # G7 036336 0051 Rev. 01; NB# 0123 Certificate # G1 036336 0054 Rev. 03; NB# 0123
Scalp Vein Set Basic UDI-DI for all variants: Scalp vein set, normal type, single-wing plate: **69230334202002b00301M8** Scalp vein set, normal type, double-wing plate: **69230334202002b00301M8**	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: Certificate # G1 036336 0054 Rev. 03; NB# 0123
Safety Scalp Vein Set Basic UDI-DI for all variants: Safety scalp vein set, safety type, single-wing plate: **69230334202002b00302MA** Safety scalp vein set, safety type, double-wing plate: **69230334202002b00302MA**	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: Certificate # G1 036336 0054 Rev. 03; NB# 0123

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
Hypodermic Needle Basic UDI-DI: Hypodermic Needle **69230334202002a00401LY**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 036336 0054 Rev. 03; NB# 0123
Safety Needle Basic UDI-DI for all variants: Safety Needle, type 1: **69230334202002a00402M2** Safety Needle, type 2: **69230334202002a00402M2** Safety Needle, type 3: **69230334202002a00402M2**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 036336 0054 Rev. 03; NB# 0123
Blood Collecting Needle Basic UDI-DI for all variants: Blood Collecting Needle, pen type: **69230334202002a00801ML** Blood Collecting Needle, double-wing type: **69230334202002a00801ML** Blood Collecting Needle, flashback type: **69230334202002a00801ML** Blood Collecting Needle, visible flashback type: **69230334202002a00801ML** Blood Collecting Needle, luer adapter: **69230334202002a00801ML** Blood Collecting Needle, pen type, with holder: **69230334202002a00801ML** Blood Collecting Needle, double-wing type, with holder: **69230334202002a00801ML** Blood Collecting Needle, flashback type, with holder: **69230334202002a00801ML**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 036336 0054 Rev. 03; NB# 0123

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
Blood Collecting Needle, visible flashback type, with holder: **69230334202002a00801ML**			
Blood Collecting Needle Basic UDI-DI: luer adapter, with holder: **69230334202002a00801ML**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2S 036336 0057 Rev. 01; NB# 0123
Safety Blood Collecting Needle Basic UDI-DI for all variants: Safety Blood Collecting Needle, pen type: **69230334202002a00802MN** Safety Blood Collecting Needle, double-wing type: **69230334202002a00802MN** Safety Blood Collecting Needle, single-wing type: **69230334202002a00802MN** Safety Blood Collecting Needle, flashback type: **69230334202002a00802MN** Safety Blood Collecting Needle, pen type, with holder: **69230334202002a00802MN** Safety Blood Collecting Needle, double-wing type, with holder: **69230334202002a00802MN** Safety Blood Collecting Needle, single-wing type, with holder: **69230334202002a00802MN**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 036336 0054 Rev. 03; NB# 0123
I.V. Catheter Basic UDI-DI for all variants: I.V. Catheter, pen type: **69230334202002b01801N8**	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: Certificate # G1 036336 0054 Rev. 03; NB# 0123

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
I.V. Catheter, butterfly-wing type **69230334202002b01801N8** I.V. Catheter, scalp vein set type **69230334202002b01801N8**			
Safety I.V. Catheter Basic UDI-DI for all variants: Safety I.V. Catheter, pen type **69230334202002b01802NA** Safety I.V. Catheter, butterfly-wing type **69230334202002b01802NA** Safety I.V. Catheter, scalp vein set type **69230334202002b01802NA**	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: Certificate # G1 036336 0054 Rev. 03; NB# 0123
Insulin Pen Needle Basic UDI-DI for all variants: Insulin Pen Needle **69230334202002a01901MY** Safety Insulin Pen Needle **69230334202002a01902N2**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 036336 0054 Rev. 03; NB# 0123
Syringe for Insulin Basic UDI-DI for all variants: Syringe for Insulin, fixed needle **69230334202002a02401ME** Syringe for Insulin, detachable needle **69230334202002a02402MG**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 036336 0054 Rev. 03; NB# 0123
Fistula Needle Basic UDI-DI for all variants: Fistula Needle, fixed wing-plate **69230334202102a02301MY**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 036336 0054 Rev. 03; NB# 0123

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
Fistula Needle, rotatable wing-plate **69230334202102a02301MY**			
Safety Fistula Needle Basic UDI-DI for all variants: Safety fistula Needle, fixed wing-plate **69230334202102a02302N2** Safety fistula Needle, rotatable wing-plate **69230334202102a02302N2**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 036336 0054 Rev. 03; NB# 0123
Dental Needle Basic UDI-DI: **69230334202102a00901NG**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 036336 0054 Rev. 03; NB# 0123
Irrigation Syringe Basic UDI-DI for all variants: Irrigation Syringe, A type, Pull ring type **69230334202101s06101VB** Irrigation Syringe, B type, Push type **69230334202101s06102VD** Irrigation Syringe, C type, Ball capsule type **69230334202101s06103VF**	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 036336 0057 Rev. 01; NB# 0123
Irrigation Needle, blunt tip Basic UDI-DI: **69230334202101s03302V2**	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G1 036336 0054 Rev. 03; NB# 0123
Dispensing Needle Basic UDI-DI for all variants: Dispensing Needle, normal type, without filtering membrane **69230334202102a04401NK**	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 036336 0057 Rev. 01; NB# 0123

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
Dispensing Needle, normal type, with filtering membrane **69230334202102a04401NK** Dispensing Needle, safety type, with filtering membrane **69230334202102a04402NM** Dispensing Needle, safety type, without filtering membrane **69230334202102a04402NM**			
Biopsy Needle Basic UDI-DI for all variants: Type I **69230334202402a04501QV**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 036336 0054 Rev. 03; NB# 0123
Huber Needle Basic UDI-DI for all variants: Normal type: **69230334202302b02701QF** Safety type: **69230334202302b02702QH**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 036336 0054 Rev. 03; NB# 0123
Percutaneous Vertebroplasty Kit Basic UDI-DI: **69230334202402a04701R7**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 036336 0054 Rev. 03; NB# 0123
Syringe Basic UDI-DI for all variants: with hypodermic needle **69230334202302a00401P5** with fixed needle **69230334202302a00402P7** with safety needle **69230334202302a00403P9**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 036336 0054 Rev. 03; NB# 0123
Infusion set Basic UDI-DI: with needle **69230334202402b00101PS**	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: Certificate # G1 036336 0054 Rev. 03; NB# 0123

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
Infusion set Basic UDI-DI: without needle **69230334202402b00102PU**	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 036336 0057 Rev. 01; NB#0123
Transfusion set Basic UDI-DI: **69230334202402b00501QE**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 036336 0054 Rev. 03; NB# 0123
Burette-type infusion set Basic UDI-DI: **69230334202402b00601QK**	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: Certificate # G1 036336 0054 Rev. 03; NB# 0123
Intravascular Catheter Introducer Basic UDI-DI: **69230334202402a04801RC**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 036336 0054 Rev. 03; NB# 0123
Disinfecting Cap Basic UDI-DI for all variants: Type 1 **69230334202402a06301QZ** Type 2 **69230334202402a06302R3**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 036336 0054 Rev. 03; NB# 0123
Sterile Syringe Basic UDI-DI for all variants: two-piece **69230334202301s06501XD** three-piece **69230334202301s06502XF**	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 036336 0057 Rev. 01; NB# 0123
Stopcock Basic UDI-DI for all variants: without infusion connector, **69230334202401s02101WL** with infusion connector **69230334202401s02102WN**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2S 036336 0057 Rev. 01; NB# 0123

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
Heparin Cap Basic UDI-DI: **69230334202401s02001WF**	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 036336 0057 Rev. 01; NB# 0123
Extension set Basic UDI-DI: normal type **69230334202401s02201WR**	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 036336 0057 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
2023-08-07	713235166 | 713268932 | 713253667	Initial issue
2024-08-22	713342840 | 713341569	Update of Device names under MDR and addition of the devices with Basic UDI-DI: 69230334202402a04501QV, 69230334202302b02701QF, 69230334202302b02702QH, 69230334202402a04701R7, 69230334202302a00401P5, 69230334202302a00402P7, 69230334202302a00403P9, 69230334202402b00101PS, 69230334202402b00102PU, 69230334202402b00501QE, 69230334202402b00601QK, 69230334202402a04801RC, 69230334202402a06301QZ, 69230334202402a06302R3, 69230334202301s06501XD, 69230334202301s06502XF, 69230334202401s02101WL, 69230334202401s02102WN, 69230334202401s02001WF, 69230334202401s02201WR
2024-08-23	713342840 | 713341569	Correction of Basic UDI-DIs of the “Sterile Syringes“