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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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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

Product Service

Add value.
Inspire trust.

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Zhejiang Kindly Medical
Devices Co., Ltd.
Mr. Jianhong Fang
Binhai Industrial Park, Longwan District
No.758, 5th Binhai Road
325025 WENZHOU, ZHEJIANG PROVINCE
PEOPLE'S REPUBLIC OF CHINA

via Email: kdlzq@126.com

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
36336	713235166 / 713268932 / 713253667	+86-10-6590-6186 jinglin.chen@tuvsud.com	+86-10-6590-6182	2023-08-07	1 of 8

TÜV SÜD Product Service GmbH
Confirmation Letter

CL 036336 0060 Rev. 00

Reference: 713235166 / 713268932 / 713253667

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:

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 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 (3a) 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)

The issuance of the first confirmation letter is free of charge. We reserve the right to invoice further copies, amendments and / or changes of the confirmation letter according to effort.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2023-08-07

TÜV SÜD Product Service GmbH
Medical and Health Services

Jeremy Chen

Mr Jinglin Chen
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

F. Eckert

Franziska Eckert
Application Reviewer

Product Service

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) 692303342021003007014U Spinal Needles (AN-S II) 692303342021003007024W Epidural Needles (AN-E) 692303342021003007034Y Combined Anaesthesia Needles (AN-S/S I) 692303342021003007452 Combined Anaesthesia Needles (AN-S/S II) 692303342021003007554 Combined Anaesthesia Needles (AN-E/S II) 692303342021003007656	☒ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate #1; G7 036336 0051 Rev. 01; NB# 0123 Certificate #2; G1 036336 0054 Rev. 03; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
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 III ☐ Class IIb implantable ☒ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: Certificate #1; G1 036336 0054 Rev. 03; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
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 III ☐ Class IIb implantable ☒ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: Certificate #1; G1 036336 0054 Rev. 03; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Disposable Needle	☐ Class III	☒ N/A	☒ Certification as follows:

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
Basic UDI-DI: Hypodermic Needle 69230334202002a00401LY	☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	or ☐ Identification of the corresponding device under MDD/AIMDD	Certificate #1; G1 036336 0054 Rev. 03; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Safety Needle Basic UDI-DI for all variants: Safety Needle, type 1: 69230334202002a00402M2 Safety Needle, type 2: 69230334202002a00402M2 Safety Needle, type 3: 69230334202002a00402M2	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: Certificate #1; G1 036336 0054 Rev. 03; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
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:	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: Certificate #1; G1 036336 0054 Rev. 03; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

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
69230334202002a00801ML Blood Collecting Needle, flashback type, with holder: 69230334202002a00801ML Blood Collecting Needle, visible flashback type, with holder: 69230334202002a00801ML			
Blood Collecting Needle, luer adapter, with holder: 69230334202002a00801ML	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: Certificate #1; G2S 036336 0057 Rev. 01; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
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:	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: Certificate #1; G1 036336 0054 Rev. 03; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

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
69230334202002a00802MN			
I.V. Catheter Basic UDI-DI for all variants: I.V. Catheter, pen type: 69230334202002b01801N8 I.V. Catheter, butterfly-wing type 69230334202002b01801N8 I.V. Catheter, scalp vein set type 69230334202002b01801N8	☐ Class III ☐ Class IIb implantable ☒ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: Certificate #1; G1 036336 0054 Rev. 03; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
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 III ☐ Class IIb implantable ☒ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: Certificate #1; G1 036336 0054 Rev. 03; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Insulin Pen Needle Basic UDI-DI for all variants: Insulin Pen Needle: 69230334202002a01901MY Safety Insulin Pen Needle: 69230334202002a01902N2	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: Certificate #1; G1 036336 0054 Rev. 03; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Syringe for Insulin Basic UDI-DI for all variants: Syringe for Insulin, fixed needle: 69230334202002a02401ME Syringe for Insulin, detachable needle: 69230334202002a02402MG	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: Certificate #1; G1 036336 0054 Rev. 03; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA#

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
			Evidence #2; CA#
Fistula Needle Basic UDI-DI for all variants: Fistula Needle, fixed wing-plate: 69230334202102a02301MY Fistula Needle, rotatable wing-plate: 69230334202102a02301MY	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: Certificate #1; G1 036336 0054 Rev. 03; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Safety Fistula Needle Basic UDI-DI for all variants: Safety fistula Needle, fixed wing-plate: 69230334202102a02302N2 Safety fistula Needle, rotatable wing-plate: 69230334202102a02302N2	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: Certificate #1; G1 036336 0054 Rev. 03; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Dental Needle Basic UDI-DI: 69230334202102a00901NG	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: Certificate #1; G1 036336 0054 Rev. 03; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Irrigation Syringe Basic UDI-DI for all variants: Irrigation Syringe, A type, Pull ring type: 69230334202101s06101VB Irrigation Syringe, B type, Push type 69230334202101s06102VD	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: Certificate #1; G2S 036336 0057 Rev. 01; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

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
Irrigation Syringe, C type, Ball capsule type: 69230334202101s06103VF			
Irrigation Needle Basic UDI-DI: 69230334202101s03302V2	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: Certificate #1; G1 036336 0054 Rev. 03; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Dispensing Needle Basic UDI-DI for all variants: Dispensing Needle, normal type, without filtering membrane: 69230334202102a04401NK Dispensing Needle, normal type, with filtering membrane: 69230334202102a04401NK Dispensing Needle, safety type, with filtering membrane: 69230334202102a04402NM Dispensing Needle, safety type, without filtering membrane: 69230334202102a04402NM	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: Certificate #1; G2S 036336 0057 Rev. 01; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

Confirmation Letter Revision History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2023/08/07	713235166 / 713268932 / 713253667	Initial issuance