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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.

Registered Office: Munich
Trade Register Munich HRB 85 742
UniCredit Bank AG · BIC HYVEDEMMXXX
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Information pursuant to § 2 [1] DL-InfoV
(Germany) at tuvsud.com/imprint

Supervisory Board:
Holger Lindner (Chairman)
Board of Management:
Walter Reithmaier (CEO)
Patrick van Welij

TÜV SÜD Product Service GmbH
Ridlerstr. 65
80339 Munich
Germany

tuvsud.com/ps
Hotline:





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

A handwritten signature in black ink, appearing to read 'Jinglin Chen'.

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) 692303342021003007014U Spinal Needles (AN-S II) 692303342021003007024W Epidural Needles (AN-E) 692303342021003007034Y Combined Anaesthesia Needles (AN-S/S I) 6923033420210030070452 Combined Anaesthesia Needles (AN-S/S II) 6923033420210030070554 Combined Anaesthesia Needles (AN-E/S II) 6923033420210030070656	<input checked="" type="checkbox"/> Class III	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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	<input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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	<input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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, vis- ible 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	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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	<input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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	<input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G1 036336 0054 Rev. 03; NB# 0123
Dental Needle Basic UDI-DI: 69230334202102a00901NG	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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	<input checked="" type="checkbox"/> Class I devices in sterile condition	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2S 036336 0057 Rev. 01; NB# 0123
Irrigation Needle, blunt tip Basic UDI-DI: 69230334202101s03302V2	<input checked="" type="checkbox"/> Class I devices in sterile condition	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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	<input checked="" type="checkbox"/> Class I devices in sterile condition	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G1 036336 0054 Rev. 03; NB# 0123
Percutaneous Vertebroplasty Kit Basic UDI-DI: 69230334202402a04701R7	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G1 036336 0054 Rev. 03; NB# 0123
Infusion set Basic UDI-DI: with needle 69230334202402b00101PS	<input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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	<input checked="" type="checkbox"/> Class I devices in sterile condition	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2S 036336 0057 Rev. 01; NB#0123
Transfusion set Basic UDI-DI: 69230334202402b00501QE	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G1 036336 0054 Rev. 03; NB# 0123
Burette-type infusion set Basic UDI-DI: 69230334202402b00601QK	<input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G1 036336 0054 Rev. 03; NB# 0123
Intravascular Catheter Introducer Basic UDI-DI: 69230334202402a04801RC	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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	<input checked="" type="checkbox"/> Class I devices in sterile condition	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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	<input checked="" type="checkbox"/> Class I devices in sterile condition	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2S 036336 0057 Rev. 01; NB# 0123
Extension set Basic UDI-DI: normal type 69230334202401s02201WR	<input checked="" type="checkbox"/> Class I devices in sterile condition	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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"