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 (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 036336 0058 Rev. 01

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 Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
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:G10 036336 0058 Rev. 01

Report No.: BJ21081202

Preceding Certificate No.: G10 036336 0058 Rev. 00

Valid from: 2022-07-01
Valid until: 2026-04-14

Date of Initial Issuance: 2021-04-15

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-07-01

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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(Class IIa and Class IIb Devices)

No. G10 036336 0058 Rev. 01

Classification:	IIa
Device Group:	A010105 - NEEDLES FOR COLLECTION UNDER VACUUM
Intended Purpose:	-

Classification:	IIa
Device Group:	A020106 - INSULIN SYRINGES, SINGLE-USE
Intended Purpose:	-

Classification:	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:	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.

Classification:	IIa
Device Group:	A010101 - HYPODERMIC NEEDLES
Intended Purpose:	-

Classification:	IIa
Device Group:	A010401 - ARTERIOVENOUS FISTULA NEEDLES
Intended Purpose:	-

Classification:	IIa
Device Group:	A010601 - CARPULE NEEDLES
Intended Purpose:	-

The validity of this certificate depends on conditions and/or is limited to the following: - none -

Revision History:

Rev.	Dated	Report
00	2021-04-15	BJ20081202

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TÜV®

EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I, Section 2 and 3 and Chapter III

TÜVRheinland®

Registration No.:	HZ 2002969-1
Manufacturer:	**Terumo (Philippines) Corporation** 124 East Main Avenue, Laguna Technopark, Binan, Laguna 4024 Philippines
EUDAMED Single Registration No.:	PH-MF-000001794
Products:	Products of class IIa: A020102 - INFUSION AND IRRIGATION SYRINGES, SINGLE-USE C010101 - PERIPHERAL I.V. CATHETERS A010101 - HYPODERMIC NEEDLES
Authorised representative(s):	Terumo Europe N.V Interleuvenlaan 40 B-3001, Leuven Belgium

Certificate history		
Revision:	Description:	Issue date:
0	Initial Certification	2023-11-06

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled. If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.:	176131510-20
Effective date:	2023-11-06
Expiry date:	2028-11-05
Issue date:	2023-11-06

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Ning Chang

Ning N. C. Chang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

10/020 d 04.08 ® TÜV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approval.

浙江康德莱医疗器械股份有限公司
ZHEJIANG KINDLY MEDICAL DEVICES CO., LTD.

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Zhejiang Kindly Medical Devices Co., Ltd
Manufacturer address and contact details	No.758,5th Binhai Road, Binhai Industrial Park, Longwan District 325000 Wenzhou, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA
Single Registration Number (SRN) (if available)	CN-MF-000007594

Authorised Representative name (if applicable)	Shanghai International Holding Corp. GmbH(Europe)
Authorised Representative address and contact details	Eiffestrasse 80, 20537 Hamburg Germany Phone: +49 89 50084-747
Single Registration Number (SRN) (if available)	DE-AR-000000001

Notified body name (if applicable)	TÜV SÜD Product Service GmbH □ See attached schedule
Notified body number (if applicable)	0123 □ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

Directive Certificate number(s) to which this confirmation is made (if applicable)	G1 036336 0054 Rev.03 □ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	2024-05-26 □ See attached schedule
End date of extended validity/transition period	2028-12-31 □ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

☑ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

☑ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
Actually, our MDR certificate was already obtained with reference to certificate No. G100363360058 Rev.01 and its valid date is from 2022-07-01 to 2026-04-14

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

☐ A QMS in accordance with Article 10(9) MDR is in place.

☑ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name: Zhejiang Kindly Medical Devices Co., Ltd.

Location & Date: Wenzhou, Zhejiang, 2024-03-06

Signature, Print Name, Title: CHEN Hong, Vice Manager of Technology Department

Contact Details (at least email): chenhong@kdlchina.com

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Disposable Needles (Hypodermic Needles) Basic UDI-DI: Normal type:69230334202002a00401LY Safety type: 69230334202002a00402M2	**Certificate#1: G1 036336 0054 Rev. 03**	**2024-05-26**	**TÜV SÜD Product Service GmbH**	**TÜV SÜD Product Service GmbH**	**2028-12-31**	**N/A**

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)