JIANGSU ZHENGKANG MEDICAL APPARATUS CO.,LTD
江苏正康医疗器械有限公司
Address：Sanhekou,Zhenglu town,Changzhou city,Jiangsu,china
TEL：+86-519-88672658 FAX：+86-519-88671088

EC Declaration of Conformity

Manufacturer: Jiangsu Zhengkang Medical Apparatus Co., Ltd
Sanhekou, Zhenglu town, Changzhou city, Jiangsu, china

Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg,Germany

Product Name: Disposable Sterile Hypodermic Needles

Model Number: 0.4mm、0.45mm、0.5mm、0.55mm、0.6mm、0.7mm、0.8mm、0.9mm、1.0mm、1.2mm
With the brand EuroMed

UMDNS code: 13929

Classification (MDD, Annex IX): IIa, rule 6
Conformity Assessment Route:Annex V.3

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC).

Standard Applied: See attached list of (harmonised – EN) standards for which documented evidence of compliance can be provided.

Report No.: 713335548

Notified Body: TÜV SUD Product Service GmbH, Ridlerstrabe 65, 80339,München, Germany

Identification number: 0123

(EC) Certificate(s): No. G2 073425 0008 Rev. 02

Expire date of the certificate: 2024-05-26

Confirmation letter: CL 073425 0012 Rev. 00

Issue date (of confirmation letter):2024-05-21

End date of extended validity: 2028-12-31

Signature:

Name: Songren. Xu

Position: General Manager

地址：江苏省常州市郑陆三河口
Address：Sanhekou,Zhenglu town,Changzhou city,Jiangsu,china
电话（TEL）：+86-519-88672658 传真（FAX）：+86-519-88671088
E-mail：info@china-zhengkang.com 邮编（Zip Code）：213115

Product Service

Mehr Wert.
Mehr Vertrauen.

TÜV SÜD Product Service GmbH · Ridlerstraße 65 · 80339 München · Deutschland

Jiangsu Zhengkang Medical Apparatus Co., Ltd.
Sanhekou, Zhenglu Town
213115 Changzhou City, Jiangsu
PEOPLE'S REPUBLIC OF CHINA

Your Ref/Name	Our Ref/Name	Tel. /E-Mail	Fax	Date	Page
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TÜV SÜD Product Service GmbH
Confirmation Letter

Reference: 713335548

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-000037484

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.

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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=cert:CL 073425 0012 Rev. 00

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-05-21

TÜV SÜD Product Service GmbH
Medical and Health Services

Jia Zhu

Mr. Jia Zhu
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Claus Matthias Mumme
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
Device 1 Infusion Sets for Single Use (with Needle) (Basic UDI -DI: 695312468101FZ)	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #G2 073425 0008 Rev.02 NB# 0123
Device 2 Sterile Hypodermic Syringes for Single Use (with Needle) (Basic UDI -DI: 695312468201G6)	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #G2 073425 0008 Rev.02 NB# 0123
Device 3 Disposable Sterile Hypodermic Needles (Basic UDI -DI: 695312468301GB)	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #G2 073425 0008 Rev.02 NB# 0123
Device 4 Scalp vein Sets (Basic UDI -DI: 695312468401GG)	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate #G2 073425 0008 Rev.02 NB# 0123

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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**
	☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
Device 5 Sterile Insulin Syringes for Single Use (Basic UDI -DI: 695312468501GM)	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #G2 073425 0008 Rev.02 NB# 0123
Device 6 Disposable Transfusion Set (with Needle) (Basic UDI -DI: 695312468601GS)	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #G2 073425 0008 Rev.02 NB# 0123

Product Service

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

Product Service

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-05-21	713335548	Initial issue

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 073425 0008 Rev. 02

Manufacturer:
Jiangsu Zhengkang Medical Apparatus Co., Ltd.
Sanhekou, Zhenglu Town
213115 Changzhou City, Jiangsu
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):
Jiangsu Zhengkang Medical Apparatus Co., Ltd.
Sanhekou, Zhenglu Town, 213115 Changzhou City, Jiangsu,
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):
Infusion Sets for Single Use (with Needle),
Sterile Hypodermic Syringes for Single Use (with Needle),
Disposable Sterile Hypodermic Needles,
Scalp vein Sets,
Sterile Insulin Syringes for Single Use,
Disposable Transfusion Set (with Needle)

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: SH19612EXT01

Valid from: 2019-11-13
Valid until: 2024-05-26

Date, 2019-11-13

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

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