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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



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 076830 0008 Rev. 02

Manufacturer:

**Changzhou Chuangjia
Medical Appliance Co., Ltd.**

Sanhekou Development Zone
Zhenglu Town
213115 Changzhou
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

**Sterile Nelaton Catheter, Sterile Suction Catheter,
Sterile Rectal Tube, Sterile Nasal Oxygen Cannula,
Sterile Nutritive Cannula(Stomach Tube, Feeding Tube),
Infusion Sets for Single Use(with Needles), Intravenous
Needles for Single Use, Sterile Syringes for Single
Use(with Needles), Auto-disable Syringes for Single
Use(with Needles), Sterile Needles for Single Use,
Sterile Masks**

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. 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:G2 076830 0008 Rev. 02

Report No.: SH2067402

Valid from: 2021-03-19

Valid until: 2024-05-26

Date, 2021-03-19

Christoph Dicks
Head of Certification/Notified Body



**Add value.
Inspire trust.**

TÜV SÜD Product Service GmbH · Ridlerstr. 65 · 80339 Munich · Germany

Changzhou Chuangjia
Medical Appliance Co., Ltd.
Sanhekou Development Zone
Zhenglu Town
213115 Changzhou
PEOPLE'S REPUBLIC OF CHINA

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
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**TÜV SÜD Product Service GmbH
Confirmation Letter
CL 076830 0014 Rev. 01**

Reference: 713300589

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-000026071

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
IBAN DE13 7002 0270 0048 8522 11
VAT ID No. DE129484267
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
Zertifizierstelle für Medizinprodukte /
Certification Body for Medical Products
Ridlerstr. 65
80339 Munich
Germany

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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_076830_0014_Rev._01

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-06-26

TÜV SÜD Product Service GmbH
Medical and Health Services

TÜV SÜD Product Service GmbH
Medical and Health Services

Haisheng Wang
Haisheng Wang (Jun 26, 2024 18:55 GMT+8)

Wang, Haisheng
Conformity Assessment Responsible (CARE)

Clara Höhneke
Clara Höhneke

Clara Höhneke
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
Device 1 Sterile Syringes for Single Use (with Needles) (Basic UDI -DI: 69579332cj00162)	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2 076830 0008 Rev. 02; NB# 0123
Device 2 Sterile Auto-disable Syringes for Single Use (with Needles) (Basic UDI -DI: 69579332cj0176H)	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2 076830 0008 Rev. 02; NB# 0123
Device 3 Sterile Needles for Single Use (Basic UDI -DI: 69579332cj0086G)	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2 076830 0008 Rev. 02; NB# 0123
Device 4 Sterile Vaginal Speculum (Basic UDI -DI: 69579332cj00264)	<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 076830 0011 Rev. 02; NB# 0123
Device 5 Sterile Urine Drainage Bag (Basic UDI -DI: 69579332cj0076E)	<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 076830 0011 Rev. 02; NB# 0123
Device 6 Sterile Medical Sampler (Basic UDI -DI: 69579332cj01165)	<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 076830 0011 Rev. 02; NB# 0123
Device 7 Sterile Gynecological Examination Set (Basic UDI -DI:	<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 076830 0011 Rev. 02; 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
69579332cj01063)			
Device 8 Disposable Irrigation Syringe (Basic UDI -DI: 69579332cj0196M)	<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 076830 0011 Rev. 02; NB# 0123
Device 9 Sterile Rectal Tube (Basic UDI -DI: 69579332cj01369)	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2 076830 0008 Rev. 02; NB# 0123
Device 10 Sterile Nasal Oxygen Cannula (Basic UDI -DI: 69579332cj0056A)	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2 076830 0008 Rev. 02; NB# 0123
Device 11 Sterile Intravenous Needles For Single Use (Basic UDI -DI: 69579332cj0096J)	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2 076830 0008 Rev. 02; NB# 0123
Device 12 Sterile Oxygen Mask (Basic UDI -DI: 69579332cj0276L)	<input type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2 076830 0008 Rev. 02; NB# 0123
Device 13 Sterile Nebulizer Mask (Basic UDI -DI: 69579332cj0286N)	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2 076830 0008 Rev. 02; NB# 0123
Device 14 Sterile Nelaton Catheter (Basic UDI -DI: 69579332cj0066C)	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2 076830 0008 Rev. 02; 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
<input checked="" type="checkbox"/> N/A	<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
2024/01/25	713300589	Initial issue
2024/06/26	713300589	Product Expansion (Device 9 – 14)