EC Certificate

TÜVRheinland®

Production Quality Assurance
MDD Annex V

Registration No.:	DD 2183016-1
Manufacturer:	Changzhou Medical Appliances General Factory Co., Ltd. Hengshanqiao Town, Wujin District, Changzhou 213119 Jiangsu P.R. China
Products:	Infusion Sets, Transfusion Sets, Syringes for Single Use, Hypodermic Needles, Scalp Vein Sets, Oxygen Masks, Sterile Nasal Oxygen Tubes, Nebulizer Masks; Aspects of manufacture concerned with securing and maintaining sterile conditions: Sterile Urine Bags, Sterile Latex Examination Gloves, Sterile Vaginal Speculum Replaces Approval, Registration No.: DD 60110015 0001

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Report No.:	15085675 010
Effective date:	2020-11-30
Expiry date:	2024-05-26
Issue date:	2020-11-30

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierstelle

Fuxiu Sheng
TÜV Rheinland LGA Products GmbH
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TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

CHANGZHOU MEDICAL APPLIANCES GENERAL FACTORY CO.,LTD

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Confirmation Letter

We,
Changzhou Medical Appliances General Factory Co., Ltd.
Hengshanqiao Town, Wujin District,
Changzhou, 213119 Jiangsu, P.R. China
SRN Number: CN-MF-000038488

Has Sent 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 **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB)designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** on NANDO.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided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, by March 20, 2023 for the relevant devices. - 2 - The transition timelines 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 (as amended by (EU) 2023/607) is December 31, 2028

Therefore, based on the above regulations and current situation, our CE certificate (Registration No.: DD 2183016-1) remains valid and will continue to be valid until December 31, 2028.

For a detailed product list, please refer to TUV's Notify Body Confirmation Letter (Reference. : CHANG PLA0 2024-05-10.order #326026333)

Changzhou Medical Appliances General Factory Co., Ltd.

May 28,2024

常州医疗器材总厂股份有限公司
中国·江苏·常州

Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

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Contact

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Date May 28, 2024

Notified Body Confirmation Letter
Reference. : CHANG_PLA0_2024-05-10; order #326026333

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 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** on NANDO, has 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 following manufacturer:

Changzhou Medical Appliances General Factory Co., Ltd.
Hengshanqiao Town, Wujin District,
Changzhou, 213119 Jiangsu,
P.R. China
SRN Number: CN-MF-000038488

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 the NB is also responsible for appropriate surveillance under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either 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, by March 20, 2023 for the relevant devices.

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The transition timelines 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 (as amended by (EU) 2023/607), are shown below:

- May 26, 2026 for Class III custom-made implantable devices
- December 31, 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- December 31, 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)

On behalf of the Notified Body

Fuxiu Sheng
Certification body

Table 1: Devices covered by this letter and for which the NB 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 at the pre-application stage)**	**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 Sets **Basic UDI-DI code: 69559003LLIFLBUZ**	Class IIa	N/A	DD 2183016-1 #0197
Infusion Sets **Basic UDI-DI code: 69559003LLIFYSXA**	Class IIa	N/A	DD 2183016-1 #0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
Syringes for Single Use **Basic UDI-DI code: 69559003LLDSLSWZ**	Class IIa	N/A	DD 2183016-1 #0197
Hypodermic Needles **Basic UDI-DI code: 69559003LLDHNSVG**	Class IIa	N/A	DD 2183016-1 #0197
Scalp Vein Sets **Basic UDI-DI code: 69559003LLSVSS3H**	Class IIa	N/A	DD 2183016-1 #0197
Oxygen Masks **Basic UDI-DI code: 69559003LLOXYM35**	Class IIa	N/A	DD 2183016-1 #0197
Sterile Nasal Oxygen Tubes **Basic UDI-DI code: 69559003LLNACAUE**	Class IIa	N/A	DD 2183016-1 #0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
Transfusion Sets **Basic UDI-DI code: 69559003LLBTSSXD**	Class IIa	N/A	DD 2183016-1 #0197
Sterile Urine Bags **Basic UDI-DI code: 69559003LLUBWVZA**	Class I devices placed on the market in sterile condition	N/A	DD 2183016-1 #0197
Sterile Urine Bags **Basic UDI-DI code: 69559003LLUBWOYU**	Class I devices placed on the market in sterile condition	N/A	DD 2183016-1 #0197
Sterile Latex Examination Gloves **Basic UDI-DI code: 69559003LLEXGLX4**	Class I devices placed on the market in sterile condition	N/A	DD 2183016-1 #0197

Table 2: Devices covered by this letter and for which the NB 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 at the pre-application stage)	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
None			

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-05-28	CHANG_CL607_2024-05-28	Initial issue