Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln.

Ningbo Jiangbei Woson Medical Instrument Co., Ltd.
No.25, Lane 300, Jinshan Road, Jiangbei District,
Ningbo 315032 Zhejiang
P.R. China

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date April 23, 2024

Notified Body Confirmation Letter
Reference. : 326013589

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:

Ningbo Jiangbei Woson Medical Instrument Co., Ltd.
No.25, Lane 300, Jinshan Road, Jiangbei District,
Ningbo 315032 Zhejiang
P.R. China
SRN Number (if available): CN-MF-000035366

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided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.

TÜV Rheinland
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Nuremberg HRB 26013
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Chairman of the
Supervisory Board

Dr.-Ing. Michael Fübi

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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

Jason Pan

Jason Pan
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**
Steam Sterilizer Basic UDI-DI: 697124689SS05PA	Class IIa	Steam Sterilizer Model: TANZO	Certificate #: HD 2058015-1 NB#: 0197
Steam Sterilizer Basic UDI-DI: 697124689SS02P4	Class IIa	Steam Sterilizer Model: TANZO	Certificate #: HD 2058015-1 NB#: 0197
Steam Sterilizer Basic UDI-DI: 697124689SS01P2	Class IIa	Steam Sterilizer Model: TANZO	Certificate #: HD 2058015-1 NB#: 0197
Steam Sterilizer Basic UDI-DI: 697124689SS04P8	Class IIa	Steam Sterilizer Model: TANDA	Certificate #: HD 2058015-1 NB#: 0197
Dental Delivery Unit Basic UDI-DI: 697124689DU01L3	Class IIa	Dental Delivery Unit Model: WOVO	Certificate #: DD 2058015-1 NB#: 0197
Dental Delivery Unit Basic UDI-DI:	Class IIa	Dental Delivery Unit Model: WOZO	Certificate #: DD 2058015-1 NB#: 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
697124689DU02L5			
Dental Delivery Unit Basic UDI-DI: 697124689DU03L7	Class IIa	Dental Delivery Unit Model: WODO	Certificate #: DD 2058015-1 NB#: 0197

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> 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
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-04-25	326013589	Initial issue

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Ningbo Jiangbei Woson Medical Instrument Co., Ltd.
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Jiangbei District, Ningbo
315032 Zhejiang
P.R. China

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date March 25, 2024

Application for: QMS
Certificate No. : HD 2058015-1
Requirement : MDD 93/42/EEC Annex II excluding (4)

Dear Madame or Sir,

Confirmation letter surveillance audit

A surveillance audit of your quality management system was performed.

The audit team confirmed that your quality management system is applied effectively with respect to the above-mentioned requirements.

The recommendation of auditor is indicated in report no. 244565668-200

This letter confirms that the above-mentioned certificate will remain valid.

Best regards,

Jason Pan
Certification body

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LGA Products GmbH

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Germany

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EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.:	HD 2058015-1
Manufacturer:	Ningbo Jiangbei Woson Medical Instrument Co., Ltd. No. 25, Lane 300, Jinshan Road, Jiangbei District, Ningbo 315032 Zhejiang P.R. China
Products:	Steam Sterilizers

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 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 II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 is required.

Report No.:	244310228-200
Effective date:	2021-04-21
Expiry date:	2024-05-26
Issue date:	2021-04-21

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Jason Pan
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Tillystraße 2 · 90431 Nürnberg · Germany

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

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