Business Stream Products
Certification Department

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TÜV Rheinland LGA Products GmbH • 51105 Köln

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Date April 29, 2024

Notified Body Confirmation Letter
Reference. : 10924237

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:

Guilin Woodpecker Medical Instrument Co., Ltd.
Information Industrial Park, Guilin National High-Tech Zone,
Guilin, 541004 Guangxi,
P.R. China
SRN Number (if available): CN-MF-000009139

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided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

Samuel Qin

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**
Ultrasonic Scaler **Basic UDI-DI:** 694484360006K2	Class IIa	N/A	Certificate # DD 601374940001 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**
Ultrasonic Periodontal Treatment Device **Basic UDI-DI:** 694484360075KM	Class IIa	N/A	Certificate # DD 60137494 0001 NB# 0197
Ultrasonic Scaler **Basic UDI-DI:** 694484360073KH	Class IIa	N/A	Certificate # DD 60137494 0001 NB# 0197
Dental Scaler and Air Polisher Model: **Basic UDI-DI:** 694484360008K6	Class IIa	N/A	Certificate # DD 60137494 0001 NB# 0197
Endo Motor and Apex Locator Unit **Basic UDI-DI:** 694484360018K9	Class IIa	Endo Motor	Certificate # DD 60137494 0001 NB# 0197
Endo Motor **Basic UDI-DI:** 694484360078KT	Class IIa	N/A	Certificate # DD 60137494 0001 NB# 0197
Apex Locator Model:	Class IIa	N/A	Certificate #

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
Basic UDI-DI: 694484360080KE			DD 601374940001 NB# 0197
Piezo Bone Sur er **Basic UDI-DI:** 694484360027KA	Class IIa	N/A	Certificate # DD 601374940001 NB# 0197
Dental Handpieces **Basic UDI-DI:** 694484360043K8	Class IIa	Contra-angle Handpieces	Certificate # DD 601374940001 NB# 0197
Dental Implantation Device **Basic UDI-DI:** 694484360032K3	Class IIa	Dental Implant	Certificate # DD 601374940001 NB# 0197
Ultrasonic Endo Activator Device Model: **Basic UDI-DI:** 694484360033K5	Class IIa	N/A	Certificate # DD 601374940001 NB# 0197
Handpieces of Dental Scaler and Air Polisher **Basic UDI-DI:** 694484360053KB	Class IIa	Ultrasonic Periodontal Treatment Device Head iece	Certificate # DD 601374940001 NB# 0197
Handpiece of Ultrasonic Scaler	Class IIa	N/A	Certificate # DD 601374940001 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
Basic UDI-DI: 694484360088KW			
Handpieces of Ultrasonic Surgical Systems **Basic UDI-DI:** 694484360048KJ	Class IIa	Handpiece of Piezo Bone Surgery	Certificate # DD 601374940001 NB# 0197
Tips of Ultrasonic Surgical Systems **Basic UDI-DI:** 694484360054KD	Class IIa	N/A	Certificate # DD 601374940001 NB# 0197
Ultrasonic Scaler Tips **Basic UDI-DI:** 694484360055KF	Class IIa	N/A	Certificate # DD 601374940001 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
Ultrasonic Periodontal Treatment Device Tips **Basic UDI-DI:** 694484360001JQ	Class IIa	N/A	Certificate # DD 601374940001 NB# 0197
Root Canal (Endodontic) Files (NITI K-File) **Basic UDI-DI:** 694484360065KJ	Class IIa	N/A	Certificate # DD 601374940001 NB# 0197
Dental Turbine Handpiece **Basic UDI-DI:** 694484360071KD	Class IIa	N/A	Certificate # DD 601374940001 NB# 0197
Dental Diode Laser Device **Basic UDI-DI:** 694484360038KF	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 2158053-1 NB#0197
Gutta Percha Obturation Device **Basic UDI-DI:** 694484360037KD	Class IIa	Hot Melting and Filling Instrument Heating and Packing Instrument	Certificate # HD 2158053-1 NB#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
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-04-29	WOODP_CL607_2024-04-29	Initial issue