

# EC Certificate

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

Registration No.: HD 2158053-1

Manufacturer: Guilin Woodpecker Medical  
Instrument Co., Ltd.  
Information Industrial Park,  
Guilin National High-Tech Zone  
Guilin  
541004 Guangxi  
P.R. China

Products: Gutta Percha Obturation Device, Dental Diode Laser Device

**TÜVRheinland**<sup>®</sup>

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.: 17039791 022

Effective date: 2021-05-19

Expiry date: 2024-05-26

Issue date: 2021-05-19



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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.

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Date July 17, 2024

### **Notified Body Confirmation Letter**

Reference. : WOODP\_PLA\_2024-03-10; order#10924486

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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Supervisory Board

Dr.-Ing. Michael Fübi

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
<b>Ultrasonic Scaler</b>  <b>Basic UDI-DI:</b> 694484360006K2	Class IIa	N/A	Certificate # DD 60137494 0001  NB# 0197
<b>Ultrasonic Periodontal Treatment Device</b>  <b>Basic UDI-DI:</b> 694484360075KM	Class IIa	N/A	Certificate # DD 60137494 0001  NB# 0197
<b>Ultrasonic Scaler</b>  <b>Basic UDI-DI:</b> 694484360073KH	Class IIa	N/A	Certificate # DD 60137494 0001  NB# 0197

<b>Device name or Basic UDI-DI (under MDR application)</b>	<b>MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)</b>	<b>If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device</b>	<b>MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification</b>
<b>Dental Scaler and Air Polisher</b>  <b>Basic UDI-DI:</b> 694484360008K6	Class IIa	N/A	Certificate # DD 60137494 0001  NB# 0197
<b>Endo Motor and Apex Locator Unit</b>  <b>Basic UDI-DI:</b> 694484360018K9	Class IIa	Endo Motor	Certificate # DD 60137494 0001  NB# 0197
<b>Endo Motor</b>  <b>Basic UDI-DI:</b> 694484360078KT	Class IIa	N/A	Certificate # DD 60137494 0001  NB# 0197
<b>Apex Locator</b>  <b>Basic UDI-DI:</b> 694484360080KE	Class IIa	N/A	Certificate # DD 60137494 0001  NB# 0197
<b>Piezo Bone Surgery</b>  <b>Basic UDI-DI:</b> 694484360027KA	Class IIa	N/A	Certificate # DD 60137494 0001  NB# 0197
<b>Dental Handpieces</b>  <b>Basic UDI-DI:</b> 694484360043K8	Class IIa	Contra-angle Handpieces	Certificate # DD 60137494 0001  NB# 0197
<b>Dental Implantation Device</b>  <b>Basic UDI-DI:</b> 694484360032K3	Class IIa	Dental Implant Unit	Certificate # DD 60137494 0001  NB# 0197
<b>Ultrasonic Endo Activator Device</b>  <b>Basic UDI-DI:</b> 694484360033K5	Class IIa	N/A	Certificate # DD 60137494 0001  NB# 0197
<b>Handpieces of Dental Scaler and Air Polisher</b>  <b>Basic UDI-DI:</b> 694484360053KB	Class IIa	Ultrasonic Periodontal Treatment Device Headpiece	Certificate # DD 60137494 0001  NB# 0197

<b>Device name or Basic UDI-DI (under MDR application)</b>	<b>MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)</b>	<b>If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device</b>	<b>MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification</b>
<b>Handpiece of Ultrasonic Scaler</b>  <b>Basic UDI-DI:</b> 694484360088KW	Class IIa	N/A	Certificate # DD 60137494 0001  NB# 0197
<b>Handpieces of Ultrasonic Surgical Systems</b>  <b>Basic UDI-DI:</b> 694484360048KJ	Class IIa	Handpiece of Piezo Bone Surgery	Certificate # DD 60137494 0001  NB# 0197
<b>Tips of Ultrasonic Surgical Systems</b>  <b>Basic UDI-DI:</b> 694484360054KD	Class IIa	N/A	Certificate # DD 60137494 0001  NB# 0197
<b>Ultrasonic Scaler Tips</b>  <b>Basic UDI-DI:</b> 694484360055KF	Class IIa	N/A	Certificate # DD 60137494 0001  NB# 0197
<b>Ultrasonic Periodontal Treatment Device Tips</b>  <b>Basic UDI-DI:</b> 694484360001JQ	Class IIa	N/A	Certificate # DD 60137494 0001  NB# 0197
<b>Root Canal (Endodontic) Files (NITI K-File)</b>  <b>Basic UDI-DI:</b> 694484360065KJ	Class IIa	N/A	Certificate # DD 60137494 0001  NB# 0197
<b>Dental Turbine Handpiece</b>  <b>Basic UDI-DI:</b> 694484360071KD	Class IIa	N/A	Certificate # DD 60137494 0001  NB# 0197
<b>Dental Diode Laser Device</b>  <b>Basic UDI-DI:</b> 694484360038KF	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 2158053- 1  NB#0197
<b>Gutta Percha Obturation Device</b>	Class IIa	Hot Melting and Filling Instrument	Certificate # HD 2158053- 1

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: 694484360037KD		Heating and Packing Instrument	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
2024-07-17	WOODP_CL607_2024-07-17	Remove model name from Table 1