

File No.: ZMN-YF-(U01)-01-001-02

Version:G

EC Declaration of Conformity

Manufacturer:

whose single Authorized Representative:

Guilin Woodpecker Medical Instrument Co., Ltd.

MedNet EC-Rep GmbH • Borkstrasse 10 • 48163 Muenster • Germany

We, the manufacturer, here with declare that the products Ultrasonic Surgical System, UMDNS-Code: 18049

Product name	Model
Piezo Bone Surgery	ULTRASURGERY, ULTRASURGERY LED
	US-II、US-II LED
	DS-II、DS-II LED
	Surgery-X、Surgery-X LED
	Surgic Touch Surgic Touch LED

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class IIa according to Annex IX of the Directive 93/42/EEC. It bears the mark

C € 0197

The product concerned has been manufactured under a quality management system according to Annex VI and Annex VII of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431, Nürnberg, Germany

Certificate No.: DD 60137494 0001 Issue date: 2019-7-16 Expiry date: 2024-5-27

following the procedure relating to the EC Declaration of Conformity set out in Annex V and Annex VII of Directive 93/42/EEC.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific Certificate of Compliance for all products concerned bearing the CE mark

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: Guilin Woodpecker Medical Instrument Co., Ltd.



桂林市啄木鸟医疗器械有限公司 GUILIN WOODPECKER Medical Instrument Co.,LTD.

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Legally binding signature, Function

Address: Information Industrial Park, Guilin National High-Tech Zone, Guilin, Guangxi, 541004 P.R. China