



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

File No.: ZMN-YF-AF7-01-001-008

Version: A

EC Declaration of Conformity

Manufacturer: Guilin Woodpecker Medical Instrument Co.,Ltd
Information Industrial Park, Guilin National High-Tech Zone, 541004 Guilin, Guangxi, PEOPLE'S REPUBLIC OF CHINA

SRN of Manufacturer: CN-MF-000009139

European Representative: MedNet EC-REP C Iib GmbH
Borkstrasse 10, 48163 Muenster, Germany

SRN of European Representative: DE-AR-000011194

Product Name: Ultrasonic Surgical System

Models: Surgical Master SE、Surgical Master、Surgic Star SE、Surgic Star

Classification: II a / Rule 9 (MDR, Annex VIII)

CND Code: Z121101

Basic UDI-DI: 694484360027KA

Conformity Assessment Route: Annex IX Chapters I and III of (EU)2017/745, MDR

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Regulations and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the Declaration of Conformity. The EU declaration of conformity is issued under the sole responsibility of the manufacture.

General applicable regulations: Medical Device Regulation, (EU)2017/745, EU RoHS Directive 2011/65/EU and Directive (EU)2015/863 .

Notified Body: TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg
Country: Germany
NB Identification number: 0197

CE Certificate No.: HZ 2158053-1

Effective date: 2023-07-31

Expire date : 2028-07-30

陳藍 2024.7.22
Complied by:

王設瑞 2024.7.22
Reviewed by:



Name: Ning Jia kang
Position: PRRC
Location: Guilin, China

Signature:

2024.7.22