

File No.: ZMN-YF-AR3-01-003

Version: A

EC Declaration of Conformity

Manufacturer:

Guilin Woodpecker Medical Instrument Co.,Ltd

Information Industrial Park, Guilin National High-Tech

Zone, Guilin, 541004 Guangxi, P.R. 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:

Gutta Percha Obturation Device

Models:

Fi-E, Fi-P, Fi-G

Classification:

II a / Rule 9 (MDR Annex VIII)

EMDN Code:

Z121101

Basic UDI-DI:

694484360037KD

Conformity Assessment Route:

Annex IX Chapters I and III of (EU)2017/745, MDR

We, the manufacturer, herewith declare under our sole responsibility that the above mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR) and other relevant Union legislation that provides for the issuing of an EU declaration of conformity. All supporting documentations are retained under the premises of the manufacturer.

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

Position: PRRC

Location: Guffin China

Name: Ning Jiakang