

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

File No.: ZMN-YF-CB1-01-001-008

Version: A.0

EC Declaration of Conformity

Manufacture

Guilin Woodpecker Medical Instrument Co., Ltd

Information Industrial Park, Guilin National High-Tech Zone, Guilin,

Guangxi, 541004 P.R. China SRN:CN-MF-000009139

European

MedNet EC-REP C IIb GmbH

Representative:

Borkstrasse 10.48163 Muenster Germany

DE-AR-000011194

Product Name:

Endo File Remover

Model:

TFRK-L

Classification (MDR, Annex VIII): Class I / Rule 5, (MDR, Annex VIII)

EMDN Code: Z1211

Basic UDI - DI: 694484360069KS

Conformity Assessment Route: Annex II, Annex 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, the manufacturer, are exclusively responsible for the Declaration of Conformity.

General applicable regulations: Medical Device Regulation, (EU)2017/745.

Name: 宇加康(Ning/Jiakang

Position: PRRC

Location: Guilin, China

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