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

File No.: ZMN-YF-FM1-01-001
Version: B.1

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
European Representative:	**MedNet EC-Rep GmbH** **Borkstrasse 10·48163 Muenster Germany**
Product Name:	Curing Light
Models:	LED.B, LED.C, LED.D, LED.E, LED.F, BUILT-IN, BUILT IN-H, LED.H, LUX V , LED.G, LUX E, LUX VI, i LED, X-CURE, O-Light, B-Cure, i LED II, O-Light II.

Classification (MDR, Annex VIII): Class I / Rule 13, (MDR, Annex VIII)
GMDN Code: 35775
UMDNS Code: 16386
UDI - DI: 694484369022LX
SRN:CN-MF-000009139
Conformity Assessment Route: Annex II, Annex III, Annex IV 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.

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

Standard

EN 60601-1 : 2014 / IEC 60601-1 : 2012
EN 60601-1-2 : 2015 / IEC 60601-1-2 : 2014
EN IEC 80601-2-60 : 2015 / IEC 80601-2-60 : 2012

Place, Date of Issue

Name: 宁加康
Position: Management representative
Location: Guilin, China
Signature: 2021.6.4

Complied by: 2021-6-4
Reviewed by: 2021.6.4