

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

File No.: ZMN-YF-(CL01)-01-001

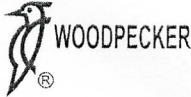

Version: A.1

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
SRN:DE-AR-000000002

Product Name: **Curing Light**

BRAND	MODEL
 DTE [®]	LED.B 、 LED.C 、 LED.D 、 LED.E 、 LED.F、 BUILT-IN C、 BUILT IN-H、 LED.H、 LED.G、 i Led、 X-Cure、 B-Cure、 i Led II、 LUX V、 LUX E、 LUX VI、 O-Light、 O-Light II
DTE [®] DBA [®] RTA [®]  ONECURE [™]	O-Star

Classification (MDR, Annex VIII): Class I / Rule 13, (MDR, Annex VIII)

GMDN Code: 35775

UMDNS Code: 16386

Basic UDI - DI: 694484369022LX

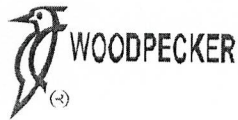
SRN: CN-MF-000009139

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.





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Standard

EN ISO 14971:2019, ISO 15223-1:2021, EN 1041:2008
EN 60601-1:2006+A12:2014, IEC 60601-1: 2012 reprint,
EN 60601-1-6:2010, EN 60601-1-2:2015, EN ISO 7405:2018,
EN ISO 10993-1:2009, EN ISO 10993-5:2009, ISO 15883-5:2021
EN ISO 17664:2017, EN ISO 17665-1:2006, EN 62471:2008,
EN 62366-1:2015, EN 62034:2012, IEC 62133-2:2017,
EN ISO 13485:2016, EN IEC 80601-2-60-2020, ISO 10650: 2018,
(EU) 2017/745, MEDDEV 2.12/1 rev.8, EN ISO 10993-10:2013,
MEDDEV 2.7/1 revision 4: CLINICAL EVALUATION

Place, Date of Issue

Name: 宁加康

Position: Management representative

Location: Guilin, China

陈燕 2021.11.3
Preparation, Date

王波 2021.11.3
Review, Date

