EC DECLARATION OF CONFORMITY TO REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 5 APRIL 2017 ON MEDICAL DEVICES (MDR)

Manufacturer:	Guilin Refine Medical Instrument Co., Ltd. No.8-3, Information Industrial Park, High-Tech Zone, Qixing District, Guilin, Guangxi, 541004, P.R.China
Medical Device:	Curing Light (GMDN [35775]) Model : MaxCure 3、MaxCure 5、MaxCure 9、A-Cure、A-Cure Plus、 MaxCure G、MaxCure H、SWAN
Basic UDI-DI	697156045RCLS8
Classification:	Class I, Rule 13, Annex VIII
Tradename:	Refine
Conformity Assessment Route:	Annex II + III

WE, GUILIN REFINE MEDICAL INSTRUMENT CO., LTD., HEREWITH DECLARE ON OUR SOLO RESPONSIBILITY THAT THE STATED MEDICAL DEVICES MEET ALL THE PROVISIONS OF THE REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 5 APRIL 2017 ON MEDICAL DEVICES;
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED: EN ISO 13485-2016/AC:2018、EN ISO 14971-2019、EN 1041-2008+A1:2013、EN 60601-1:2006/A1:2013/AC:2014、EN 60601-1-2-2015、EN 60601-1-6-2010+A1-2015、EN 80601-2-60-2015、EN ISO 7405-2018、EN ISO 10993-1-2009、EN ISO 10993-5-2009、EN ISO 10993-10-2013、EN ISO 17664-2017、EN ISO 17665-1-2006、EN ISO 17665-2-2009、EN ISO 10650-2018、EN 62304-2006/A1:2015、EN ISO 9687-2015+A1-2018、EN ISO 7494-1-2018、EN ISO 15223-1-2016、IEC 62366-1-2015

Identification Number	CE	Start Of CE-Marking:	2021-06-30
EC REP European Representative	MedNet EC-REP GmbH Borkstrasse 10, 48163 Muenster, Germany		
SRN of the Authorized Representative	DE-AR-000000002		

Place, Date Of Declaration: Signature: (Editor)	Guilin, 2021-06-30 Name: Chen Judong Position: Management representative	Place, Date Of Declaration: Signature: (Approver)	Guilin, 2021-06-30 Name: Mu Lianbin Position: General manager