EU Declaration of Conformity

TO REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

Manufacturer:	Name: Guilin Refine Medical Instrument Co., Ltd. Address: No.8-3, Information Industrial Park, High-Tech Zone, Qixing District, 541004 Guilin, Guangxi, PEOPLE'S REPUBLIC OF CHINA SRN: CN-MF-000012204
European Representative:	Name: MedNet EC-REP C IIb GmbH Address: Borkstraße 10, 48163 Münster, Germany SRN: DE-AR-000011194
Product Name:	Curing Light
Model:	MaxCure3, MaxCure5, MaxCure7, MaxCure9, SWAN, SWAN+, A-Cure, A-Cure Plus, MaxCureG, **MaxCure1**
GMDN Code:	35775
Basic UDI-DI:	697156045RCLS8
Intended Use:	Curing Light is intended for use by trained dental professionals for the purpose of light curing dental resins and composites.
Risk Class:	Class I
Classification Rule:	Rule 13 in Chapter III of Annex VIII of the Regulation (EU) 2017/745
Conformity Assessment Route	Annex II & III of the Regulation (EU) 2017/745
We herewith declare that the above-mentioned product(s) meet the Regulation (EU) 2017/745 of THE EUROPEAN PARLIAMENT AND OF THE COUNCIL and the transposition into national law. All supporting documentation is retained at the premises of the manufacturer. We, the manufacturer, are exclusively responsible for the DoC. Every article we sell is covered by a technical file. Technical files are provided to the European Authorized Representative and kept up to date by us.	
Applied Standards:	EN ISO 13485:2016/AC:2018, MEDDEV.2.7.1 Rev4, EN ISO 14971:2019, IEC 62304:2006/A1:2015, IEC 62366-1:2015+AMD1:2020, IEC 60601-1:2005+A1:2012, IEC 60601-1:2005+A2:2020, IEC 60601-1-2:2014+A1:2020, IEC

	60601-1-2:2014, IEC 80601-2-60:2019, ISO 10650:2018, EN ISO 9687:2015/A1:2018, EN ISO 15223-1:2021, EN ISO 20417:2021, EN ISO 7405:2018, EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-10:2013, EN ISO 17664:2017, EN ISO 17665-1:2006, ISO/TS 17665-2:2009, EN 62506:2013
Place, Date of Issue:	Guilin, Guangxi, 2025-10-15
Signature:	Name: Su Qin Function: Management representative