

DECLARATION OF CONFORMITY

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We, **Dentmate Technology Co., Ltd.,** 8F, No.8-11, Sec. 1, Zhongxing Road, Wugu District, New Taipei City 24872, Taiwan.

We declare on our own responsibility that the medical device and this DoC. All supporting documentation is retained at the premises of the manufacturer.

Product Description: Dental Curing Light

Trade Name: LEDEX

Basic UDI-DI: 471987392001JE

Model:

Model Name	REF
WL-070	3100-1001
WL-070+	3103-1001
WL-070+ORTHO	3105-1001
WL-090	3101-1001
WL-090+	3102-1001

Classification: Class I

according to Annex VIII of the regulation (EU) 2017/745: rule 1 and rule 13

meets all the provisions of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, which apply to it.

Applied harmonized Standards:

EN 60601-1 / EN 60601-1-2 / EN ISO 15223-1 / EN 1041 / ISO 14971 / ISO 13485

Conformity assessment procedure:

Class I device, Annexes II, III of Regulation MDR 2017/745

European authorized representative:

MedNet EC-REP GmbH

Borkstrasse 10 • 48163 Muenster Germany

SRN of the authorized representative: Not yet available.

Dentmate Technology Co., Ltd.

8F, No.8-11, Sec. 1, Zhongxing Road, Wugu District, New Taipei City 24872 Taiwan

President / Cheng-Feng Chou Taipei / Taiwan, April 22, 2021