

203-605, 397 Seokcheon-ro, Ojeong-gu, Bucheon-si, Gyeonggi-do, Republic of Korea Tel : +82 32 624 3277 Fax: +82 32 624 3278 sales@maxdental.co.kr

www.maxdental.co.kr

## **Declaration of Conformity**

■ Document No : MD-DOC-18003

■ Type of equipment : Noblesse Wireless LED Curing Light

■ Model No : NB11-100

■ Manufacturer : Max Dental Co., Ltd.

■ Address : 203-605, Bucheon Techno-Park Ssang Yong 3cha

397, Seokcheon-ro, Ojeong-gu, Bucheon-si, Gyeonggi-do, Republic of Korea, 14449

We, the manufacturer, declare and ensure with sole responsibility that the below mentioned Medical Device(s) meet(s) the provisions of Council Directive 93/42/EEC (Medical Device Directive) which apply to them. The obligations laid down in Annex VII excluding section 5 have been fulfilled.

| <u>Product Name</u>                | <u>Product Code</u><br>(or other unambiguous reference) |
|------------------------------------|---|
| Noblesse Wireless LED Curing Light | 16-386  |
|                                    |   |
|                                    |   |

The standards relevant for the evaluation of EMC requirements are as follows:

Test Standards: CISPR 11:2009 + A1:2010 – Industrial, Scientific and Medical

Not-life supporting equipment, Class B

IEC 60601-1:2005 + CORR. 1(2006) + CORR. 2(2007)

Date of issue: October 2, 2013

Classification of Medical Device: Class I

We explicitly designate MDSS GmbH to act as our sole Authorized Representative in the European Union for the above indicated product(s).

MAXDENTAL CO., LTD

203-605, Bucheon Technopark Ssangyong 3rd, #36-1, Samjeong-dong, Ojeong-gu, Bucheon-si,

Gyeonggi-do, KOREA

PRESIDENT KIM JONG NAM

Jeffrey Kang / Managing Director

Printed Name / Title

■ Date of issue : October 12th, 2018