



J. MORITA MFG. CORP.

680 HIGASHIHAMA MINAMI-CHO, FUSHIMI-KU, KYOTO 612-8533, JAPAN

EC DECLARATION OF CONFORMITY

We

J. Morita Manufacturing Corporation
680 Higashihama Minami-cho, Fushimi-ku, Kyoto, 612-8533 Japan

declare under own responsibility, that the product:

Kind of product : Dental Curing Light

Model : VL-7

Type: CE

Medical product Class : Class I

is in compliance with the European Directive :

93/42/EEC

“ Council Directive of 14 June 1993 on the approximation of the laws of the Member States concerning medical devices.”

The technical documents as submitted and full compliance with the standards listed below proves the conformity with the essential requirements of the above-mentioned EC Directive.

IEC 60601-1:1988 + A1:1991 + A2:1995	<i>General requirements for safety</i>
IEC 60601-1-2:2001 + A1:2005	<i>Electromagnetic compatibility</i>
IEC 60601-1-4:1996 + A1:1999	<i>Programmable electrical medical systems</i>
IEC 60825-1:1993+A1:1997+A2:2001	<i>Safety of laser products</i>
ISO 10993-1:2003	<i>Biological evaluation - Evaluation and testing</i>
ISO 10993-5:1999	<i>Tests for in vitro cytotoxicity</i>
ISO 10993-12:2002	<i>Sample preparation and reference material</i>
ISO 14971:2000 + A1:2003	<i>Application of risk management to medical devices</i>
EN 980:2003	<i>Graphical symbols for use in the labeling</i>
EN 1041:1998	<i>Information supplied by the manufacturer</i>
UL 60601-1	
CAN/CSA C22.2 No.601.1-M90	

EU authorized representative : Medical Technology Promedt Consulting
Altenhofstrasse 80,
66386 St. Ingbert, Germany

Kyoto, Japan, 2007-03-29

(Place, date)

Sekiya Ogino
Managing Director