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 root canal measuring and Treatment units**
Model :	**DP-ZX**
Type:	**RCM-EX, TR-EX**
Medical product Class :	**IIa Rule 9**

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 full compliance with the standards listed below proves the conformity with the essential requirements of the above-mentioned EC Directive as separately recorded in our technical documents.

Standard number	Contents
IEC 60601-1:1988 + A1:1991 + A2:1995	*General requirements for safety*
IEC 60601-1-2:2001 + A1:2005	*Electromagnetic compatibility*
IEC 60601-1-4:1996 + A1:1999	*Programmable electrical medical systems*
IEC 60825-1:1993+A1:1997+A2:2001	*Safety of laser products*
ISO 7785-2:1995	*Dental handpieces -Straight and geared angle handpieces*
ISO 11498:1997	*Dental low-voltage electrical motors*
ISO 10993-1:2003	*Biological evaluation - Evaluation and testing*
ISO 10993-5:1999	*Tests for in vitro cytotoxicity*
ISO 10993-12:2002	*Sample preparation and reference material*
ISO 14971:2000 + A1:2003	*Application of risk management to medical devices*
EN 980:2003	*Graphical symbols for use in the labeling*
EN 1041:1998	*Information supplied by the manufacturer*
EN 1639:2004	*Medical devices for dentistry- Instruments*
EN 1640:2004	*Medical devices for dentistry- Equipment*

The compliance with requirements of Annexes II has been proven by the following certificate.

Name of certificate: Approval EC Directive 93/42/EEC Annex II, Article 3, Full Quality Assurance System, Medical Devices
Registration No: HD 60016107 0001
Notified Body: TÜV Rheinland Product Safety GmbH
Am Grauen Stein, D-51105 Köln

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

Kyoto, Japan
2007-03-28

(Place, date)

Sekiya Ogino

Ogino, Sekiya
Director