

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 :	TR-ZX	
Type:	CE	
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	<i>General requirements for safety</i>
IEC 60601-1-2:2001 + A1:2005	<i>Electromagnetic compatibility</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>
German commodity goods ordinance	

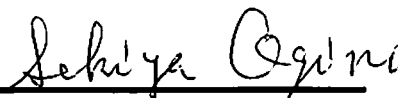
The compliance with requirements of Annexes II has been proven by the following certificate.

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
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Kyoto, Japan
2006-11-17

(Place, date)



Ogino, Sekiya
Director