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 : High-speed air turbine handpieces for dental treatment

Model :	*WITH LIGHT*		*WITHOUT LIGHT*	
	PAR-4HE-O	PAR-4HS-O	PAR-4HE	PAR-4HS
	PAR-4HEX-O	PAR-4HX-O	PAR-4HEX	PAR-4HX
	PAR-4HEX-O-KV	PAR-4HX-O-KV	PAR-4HEX-KV	PAR-4HX-KV
	PAR-4HEX-O-NK	PAR-4HX-O- NK	PAR-4HEX- NK	PAR-4HX- NK
	PAR-4HEX-O-SR	PAR-4HX-O-SR	PAR-4HEX-SR	PAR-4HX-SR
	PAR-4HEX-O-WH	PAR-4HX-O-WH	PAR-4HEX-WH	PAR-4HX-WH

Medical product Class : II a 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

IEC 60601-1:1988 + A1:1991 + A2:1995
IEC 60601-1-2:2001
ISO 14971:2000+A1:2003
ISO7785-1:1997
EN980:2003
EN1041:1998
EN 1639:2004
EN 1640:2004
FDA G95-1
ISO 10993-1:2003
AAMI TIR No.12
ISO 10993-5:1999
ISO 9168:1991 / EN29168:1994

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, 2007-1-15

(Place, date)

Sekiya Ogino

Sekiya Ogino
Managing Director

TEL 81-75-611-2141 FAX 81-75-622-4595