

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

Product Name: TWINPOWERTURBINE 4H

Model : It is displayed by the composition shown in the following.

Head Size

- E= Standard Torque
- EX= Standard Torque plus Zero Suck Back
- S= High Torque
- X= High Torque plus Zero Suck Back
- MX=Miniture and Zero Suck Back
- UEX=ULTRA Standard Torque plus Zero Suck Back
- UMX=ULTRA Miniture plus Zero Suck Back

Head Angle (to vertical)

- No Symbol=75°
- -45=45°
- -90=90°

PAR-4H*O-*-*

Light

- O=with light
- No Symbol=without light

Couplings

- No Symbol=Morita CP4-* Coupling
- KV=KaVo MULTIflex Coupling
- NK=NSK MachLite/ Phatelus Coupling
- WH=W&H Roto Quick Coupling
- SR=SIRONA R/F Coupling
- YS=YOSHIDA Coupling
- K=Morita FS-I Tubing
- OT=OSADA TORON Tubing
- OF=OSADA FINE Tubing
- B=ISO9168 TYPE3 connection

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 compliance with requirements of EC Directive 93/42/EEC Annex II, Article3 has been approved by the following notified body.

Notified Body: TÜV Rheinland LGA Products GmbH
Tillystrasse 2, 90431 Nuremberg Germany
Identification No.: 0197

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

This declaration of conformity is related to each product release document.

Kyoto, Japan
2012-10-30

(Place, date)

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

Sekiya Ogino

Ogino, Sekiya
Executive Director

There are 53 following Model and 6 couplings by the composition on 2012-10-30

PAR-4H*		Coupling	
	Registered Code Registered Name	Registered Code Registered Name	
1	H600 PAR-4HE	H604 CP4	
2	H601 PAR-4HE-O	H605 CP4-O	
3	H602 PAR-4HS	H607 CP4-WO	
4	H603 PAR-4HS-O	H687 CP5-O	
5	H618 PAR-4HX	H704 CP4-LD	
6	H619 PAR-4HX-O	H707 CP4-WLD	
7	H628 PAR-4HX-O-KV		
8	H629 PAR-4HX-O-NK		
9	H630 PAR-4HX-O-WH		
10	H631 PAR-4HX-O-SR		
11	H636 PAR-4HEX-O-KV		
12	H637 PAR-4HEX-O-NK		
13	H638 PAR-4HEX-O-WH		
14	H639 PAR-4HEX-O-SR		
15	H640 PAR-4HEX-O		
16	H665 PAR-4HMX		
17	H666 PAR-4HMX-O		
18	H667 PAR-4HMX-O-KV		
19	H668 PAR-4HMX-O-NK		
20	H669 PAR-4HMX-O-WH		
21	H670 PAR-4HMX-O-SR		
22	H677 PAR-4HEX-K		
23	H678 PAR-4HEX-O-45		
24	H679 PAR-4HMX-O-45		
25	H680 PAR-4HX-O-45		
26	H681 PAR-4HX-O-YS		
27	H682 PAR-4HEX-O-YS		
28	H683 PAR-4HMX-O-YS		
29	H684 PAR-4HEX-O-90		
30	H685 PAR-4HEX-O-KV90		
31	H686 PAR-4HEX-O-YS90		
32	H695 PAR-4HEX-O-KV45		
33	H698 PAR-4HEX		
34	H703 PAR-4HX-O (4W)		
35	H713 PAR-4HEX-O-OT		
36	H714 PAR-4HUEX-O		
37	H715 PAR-4HUMX-O		
38	H716 PAR-4HEX-O-OF		
39	H717 PAR-4HUEX-O-KV		
40	H718 PAR-4HUEX-O-NK		
41	H719 PAR-4HUEX-O-WH		
42	H720 PAR-4HUEX-O-SR		
43	H721 PAR-4HUEX-O-YS		
44	H722 PAR-4HUEX-O-OT		
45	H723 PAR-4HUEX-O-OF		
46	H724 PAR-4HUMX-O-KV		
47	H725 PAR-4HUMX-O-NK		
48	H726 PAR-4HUMX-O-WH		
49	H727 PAR-4HUMX-O-SR		
50	H728 PAR-4HUMX-O-YS		
51	H729 PAR-4HUMX-O-OT		
52	H730 PAR-4HUMX-O-OF		
53	H733 PAR-4HEX-B		

These models are described generally as "PAR-4H" in this Technical Documentation.

However, when identification is necessary in model tests, they are described by their own model name.

CP4 series are the couplings for connecting the Twin Power Turbine 4H handpiece to an ISO9168 Type 3 (c) tube.