

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4 Full Quality Assurance System Medical Devices

Registration No.: HD 60147054 0001

Report No.: 12031341 017

Manufacturer: J. MORITA MFG. CORP.

680 Higashihama Minami-cho, Fushimi-ku

Kyoto

612-8533 Japan

Products: Electrical and Air Driven Equipment for Dentistry and

Diagnostic Imaging

(see attachments for products and site included)

Replaces Approval, Registration No.: HD 60123202 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date:

2020-04-20

Date:

2020-04-20

Notified Body

Takashi Matsuda

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC
concerning medical devices with the identification number 0197.

TÜVRheinland



Doc. 1/2, Rev.0

TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Attachment to Certificate

Registration No.:

HD 60147054 0001

Report No.:

12031341 017

Manufacturer:

J. MORITA MFG. CORP.

680 Higashihama Minami-cho, Fushimi-ku

Kyoto

612-8533 Japan

Products included:

- Computer tomographs
- X-ray units
- Dental handpieces
- Dental treatment units
- Air-powered scalers for dental treatment
- Dental root canal measuring and treatment units
- Dental air motors
- Dental electric motors
- Dental laser systems
- Ultrasonic dental scaling systems

Notified Body

TÜVRheinland

lifizierungsste

Date: 2020-04-20

10/020 d 04 08 🐵 TÜV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approval

Takashi Matsuda



Doc. 2/2, Rev.0

TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Attachment to Certificate

Registration No.:

HD 60147054 0001

Report No.:

12031341 017

Manufacturer:

J. MORITA MFG. CORP.

680 Higashihama Minami-cho, Fushimi-ku

Kyoto

612-8533 Japan

Manufacturing Sites included:

J. MORITA MFG. CORP. KUMIYAMA FACTORY
190 Shintamaki, Ichida, Kumiyama-cho, Kuze-gun,
Kyoto 613-0022, Japan
Product:

-Dental treatment units

J. MORITA MFG. CORP. TOTTORI FACTORY 608 Tani, Kurayoshi, Tottori 682-0954, Japan Product:

-Dental handpieces

-X-ray Units

Notified Body

Takashi Matsuda

Date: 2020-04-20

0/020 d 04 08 & TUV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approva

Business Stream Products Certification Department



Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

J. MORITA MFG. CORP. 680 Higashihama Minami-cho, Fushimi-ku, Kyoto 612-8533, Japan Contact

Tel. +49 911 655-5225

Mail: medical-products@de.tuv.com

Date May 16, 2024

Notified Body Confirmation Letter

Reference.

: JMORI CL607 2024-05-16

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

J. MORITA MFG. CORP. 680 Higashihama Minami-cho, Fushimi-ku, Kyoto 612-8533, Japan SRN Number (if available): JP-MF-000023000

The devices covered by the formal application and the written agreement mentioned above are identified in the tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by March 20, 2023 for the relevant devices.

TÜV Rheinland LGA Products GmbH

Am Grauen Stein 51105 Köln Germany

Headquarter

Tillystraße 2 90431 Nuremberg

Board of Management

Dipl.-Ing. Thomas Weigand, Spokesman

Dipl.-Kfm. Dr. Jörg Schlösser

Nuremberg HRB 26013 VAT No.: DE 811835490

Chairman of the Supervisory Board

Dr.-Ing. Michael Fübi

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- May 26, 2026 for Class III custom-made implantable devices
- December 31, 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- December 31, 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body

Nasu Yang Certification body

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre- application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Tri Auto ZX2	lla	N/A	HD 60147054 0001 #01972) (Model: TR-ZX2)
TWINPOWER TURBINE p TWINPOWER TURBINE 4H	lla	N/A	Same as above (Model: PAR-DI and PAR-4H)
Veraview X800	llb non-implantable	N/A	Same as above (Model: X800)
Adverl SH	llb non-implantable	AdvErl EVO	Same as above (Model: MEY-1-A)
Root ZX mini Endostar Navigator	lla	N/A	Same as above (Model: RCM-7)
Tri Auto mini Endostar Providor	lla	N/A	Same as above (Model: TR-CM)
TORX	lla	N/A	Same as above (Model: TORX)
Root ZX mini U	lla	N/A	Same as above (Model: RCM-7-Cu)
Solfy U	lla	N/A	Same as above (Model: SC-U)
Dentaport ZX	lla	N/A	Same as above (Model: DP-ZX)

MS-0048822, rev.

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the preapplication stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
TORQTECH	lla	N/A	Same as above (Model: TORQTECH)
Veraview IC-5	llb non-implantable	N/A	Same as above (Model: XDP1)
Veraviewepocs	llb non-implantable	N/A	Same as above (Model: X550)
3D Accuitomo	llb non-implantable	N/A	Same as above (Model: MCT-1)
Veraview iX	llb non-implantable	N/A	Same as above (Model: V080)

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre- application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/05/16	JMORI_CL607_2024-05-16	Initial issue



Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and/or¹
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	J. MORITA MFG. COPR.
Manufacturer address and contact details	680 Higashihama Minami-cho, Fushimi-ku Kyoto 612-8533 Japan
Single Registration Number (SRN) (if available)	JP-MF-000023000

Authorised Representative name (if applicable)	Medical Technology Promedt Consulting GmbH
Authorised Representative address and contact details	Ernst-Heckel-Straße 7 66386 St. Ingbert, Germany
Single Registration Number (SRN) (if available)	DE-AR-00000085

Notified body name (if applicable)	TÜV Rheinland LGA Products GmbH □ See attached schedule
Notified body number (if applicable)	0197 □ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	HD 60147054 0001

¹ The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.



Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	2024-05-26 □ See attached schedule
End date of extended validity/transition period	2028-12-31 □ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed Directive Certificate (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met and/or²
- the listed device(s) in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

Directive Certificate(s) as listed above or in the attached so	scheau	aπacned so	ve or in the aπaci	as listed	e(S)	Certificate	Directive	
--	--------	------------	--------------------	-----------	------	-------------	-----------	--

•			e Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were 26 May 2021 and have not been withdrawn afterwards.
	Ch	oose	applicable statements:
		Exp	pired before 20 March 2023:
			Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)
			oose one of the following statements only if a derogation per Article 59(1) or a requirement Article 97(1) has been granted by a Competent Authority:
			Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be

² The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body



in place in accordance with	Section 4.3,	second	subparagraph	of Annex	VII MDI	R before
26 September 2024.						

□ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

■ Expired/expires after 20 March 2023:

Choose one applicable statement:

- Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

Upclassified devices

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

- □ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- □ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

Quality Management System (QMS)

Choose one applicable statement:

- ☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
- A QMS in accordance with Article 10(9) MDR is in place.
- ☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

> Device(s) as listed in the attached schedule

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.



Signed for and on behalf of the manufacturer:

Full Company Name: J. MORITA MFG. CORP. Location & Date: Kyoto, Japan 2024-04-17

Signature:

Print Name, Title: Tetsuzo Ito, Deputy General Manager

Contact Details (at least email): t-ito@jmorita-mfg.co.j



Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

re End date of Substitute re extended Device(s) ransition period		GA <u>2028-12-31</u> <u>N/A</u>	GA 2028-12-31 N/A	GA 2028-12-31 N/A	GA 2028-12-31 Adverl SH	GA 2028-12-31 N/A	
Notified Body name and number where the MDR application was lodged/contract signed	(if applicable)	TÜV Rheinland LGA Products GmbH (0197)	TÜV Rheinland LGA Products GmbH (0197)	TÜV Rheinland LGA Products GmbH (0197)	TÜV Rheinland LGA Products GmbH (0197)	TÜV Rheinland LGA Products GmbH	
Notified Body name and number that issued the Directive Certificate (if applicable)	:	TÜV Rheinland LGA Products GmbH (0197)	TÜV Rheinland LGA Products GmbH (0197)	TÜV Rheinland LGA Products GmbH (0197)	TÜV Rheinland LGA Products GmbH (0197)	TÜV Rheinland LGA Products GmbH	
Original expiry date as indicated on the Directive	(s) prior to the extension of the validity (if applicable)	2024-05-26	<u>2024-05-26</u>	2024-05-26	2024-05-26	2024-05-26	
Directive Certificate number(s) to which this confirmation is made	(if applicable)	HD 60147054 0001	HD 60147054 0001	HD 60147054 0001	HD 60147054 0001	HD 60147054 0001	
Identification of the device(s)³ (e.g., device name, family/group name device model or catalogue number)		Tri Auto ZX2	TWINPOWER TURBINE P TWINPOWER TURBINE 4H	Veraview X800	Adveri EVO	Root ZX mini Endostar Navigator	

³ for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)



		2000			70 07 0000	ALIA
ZYOL	0001	2024-03-20	Products GmbH (0197)	Products GmbH (0197)	16-21-9202	Y)
Root ZX mini U	HD 60147054 0001	<u>2024-05-26</u>	TÜV Rheinland LGA Products GmbH (0197)	TÜV Rheinland LGA Products GmbH (0197)	2028-12-31	N/A
Solfy U	HD 60147054 0001	2024-05-26	TÜV Rheinland LGA Products GmbH (0197)	TÜV Rheinland LGA Products GmbH (0197)	2028-12-31	<u>N/A</u>
Dentaport ZX	HD 60147054 0001	2024-05-26	TÜV Rheinland LGA Products GmbH (0197)	TÜV Rheinland LGA Products GmbH (0197)	2028-12-31	N/A
TORQTECH	HD 60147054 0001	2024-05-26	TÜV Rheinland LGA Products GmbH (0197)	TÜV Rheinland LGA Products GmbH (0197)	2028-12-31	N/A
Veraview IC-5	HD 60147054 0001	<u>2024-05-26</u>	TÜV Rheinland LGA Products GmbH (0197)	TÜV Rheinland LGA Products GmbH (0197)	2028-12-31	N/A
<u>Veraviewepocs</u>	HD 60147054 0001	<u>2024-05-26</u>	TÜV Rheinland LGA Products GmbH (0197)	TÜV Rheinland LGA Products GmbH (0197)	2028-12-31	N/A
3D Accuitomo	HD 60147054 0001	2024-05-26	TÜV Rheinland LGA Products GmbH (0197)	TÜV Rheinland LGA Products GmbH (0197)	2028-12-31	<u>N/A</u>
<u>Veraview iX</u>	HD 60147054 0001	<u>2024-05-26</u>	TÜV Rheinland LGA Products GmbH (0197)	TÜV Rheinland LGA Products GmbH (0197)	2028-12-31	N/A

J.MORITA MFG.CORP.

680 Higashihama Minami-cho, Fushimi-ku, Kyoto 612-8533, Japan

EC DECLARATION OF CONFORMITY

We

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

declare under own responsibility, that the product: Kind of product: High-speed air turbine handpices 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 Head Angle (to vertical) · S= High Torque • X= High Torque plus Zero Suck Back • MX=Miniture and Zero Suck Back No Symbol=75° -45=45° ·UEX=ULTRA Standard Torque plus Zero Suck Back · -90=90° *UMX=ULTRA Miniture plus Zero Suck Back PAR-4H*OLight -No Symbol=Morita CP4-* Coupling O=with light -KV=KaVo MULTIflex Coupling No Symbo⊨without light -NK=NSK MachLite/ Phatelus Coupling -WH=W&H Roto Quick Coupling -SR=SIRONA R/F Coupling -YS=YOSHIDA Coupling -K=Morita FS-1 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)

Ogino, Sekiya Executive Director

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

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

	PAR-4H*	
	Registered Code	Registered Name
1	H600	PAR-4HE
2	H601	PAR-4HE-O
3	H602	PAR-4HS
4	H603	PAR-4HS-0
5	H618	PAR-4HX
6	H619	PAR-4HX-0
7	the state of the s	PAR-4HX-0-KV
	H628	
8	H629	PAR-4HX-O-NK
9	H630	PAR-4HX-O-WH
10	H631	PAR-4HX-0-SR
11	H636	PAR-4HEX-0-KV
12	H637	PAR-4HEX-0-NK
13	H638	PAR-4HEX-O-WH
14	H639	PAR-4HEX-0-SR
15	H640	PAR-4HEX-0
16	H665	PAR-4HMX
17	H666	PAR-4HMX-0
18	H667	PAR-4HMX-O-KV
19	H668	PAR-4HMX-O-NK
20	H669	PAR-4HMX-O-WH
		PAR-4HMX-0-SR
21	H670	PAR-4HEX-K
22	H677	
23	H678	PAR-4HEX-0-45
24	H679	PAR-4HMX-0-45
25	H680	PAR-4HX-0-45
26	H681	PAR-4HX-0-YS
27	H682	PAR-4HEX-0-YS
28	H683	PAR-4HMX-0-YS
29	H684	PAR-4HEX-O-90
30	H685	PAR-4HEX-O-KV90
31	H686	PAR-4HEX-O-YS90
32	H695	PAR-4HEX-0-KV45
33	H698	PAR-4HEX
34	H703	PAR-4HX-0 (4W)
35	H713	
36	H714	PAR-4HEX-0-OT PAR-4HUEX-0
37	H715	PAR-4HUMX-0
38	H716	
39	The Party of the P	PAR-4HEX-O-OF
	H717	PAR-4HUEX-O-KV
40	H718	PAR-4HUEX-O-NK
41	H719	PAR-4HUEX-0-WH
42	H720	PAR-4HUEX-O-SR
43	H721	PAR-4HUEX-0-YS
44	H722	PAR-4HUEX-0-OT
45	H723	PAR-4HUEX-0-OF
46	H724	PAR-4HUMX-0-KV
47	H725	PAR-4HUMX-0-NK
48	H726	PAR-4HUMX-0-WH
49	H727	PAR-4HUMX-0-SR
50	H728	PAR-4HUMX-0-YS
51	H729	PAR-4HUMX-0-OT
52	H730	
53	H733	
J	11/00	PAR-4HEX-B

Coupling	
Registered Code	Registered Name
H604	CP4
H605	CP4-0
H607	CP4-WO
H687	CP5-0
H704	CP4-LD
H707	CP4-WLD

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.