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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Notified Body

T. Matsuda

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.

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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Notified Body

Date: 2020-04-20

Takashi Matsuda

TÜVRheinland®

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

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Notified Body

Date: 2020-04-20

T. Matsuda

Takashi Matsuda

Business Stream Products
Certification Department

TÜVRheinland®
LGA
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

Phone. +49 911 655 5225
Fax +49 911 655 5226
service@de.tuv.com
www.tuv.com/safety

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	IIa	N/A	HD 60147054 0001 #01972) (Model: TR-ZX2)
TWINPOWER TURBINE p TWINPOWER TURBINE 4H	IIa	N/A	Same as above (Model: PAR-DI and PAR-4H)
Veraview X800	IIb non-implantable	N/A	Same as above (Model: X800)
Adverl SH	IIb non-implantable	AdvErl EVO	Same as above (Model: MEY-1-A)
Root ZX mini Endostar Navigator	IIa	N/A	Same as above (Model: RCM-7)
Tri Auto mini Endostar Providor	IIa	N/A	Same as above (Model: TR-CM)
TORX	IIa	N/A	Same as above (Model: TORX)
Root ZX mini U	IIa	N/A	Same as above (Model: RCM-7-Cu)
Solfy U	IIa	N/A	Same as above (Model: SC-U)
Dentaport ZX	IIa	N/A	Same as above (Model: DP-ZX)

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
TORQTECH	IIa	N/A	Same as above (Model: TORQTECH)
Veraview IC-5	IIb non-implantable	N/A	Same as above (Model: XDP1)
Veraviewepocs	IIb non-implantable	N/A	Same as above (Model: X550)
3D Accuitomo	IIb non-implantable	N/A	Same as above (Model: MCT-1)
Veraview iX	IIb 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

MORITA

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/or*[1]
- 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-000000085

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 □ See attached schedule

[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/or*[2]
- 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 schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *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)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per 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 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.

■ 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:

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

[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)

TORX	HD 60147054 0001	2024-05-26	TÜV Rheinland LGA Products GmbH (0197)	TÜV Rheinland LGA Products GmbH (0197)	2028-12-31	N/A
Root ZX mini U	HD 60147054 0001	2024-05-26	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	N/A
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	2024-05-26	TÜV Rheinland LGA Products GmbH (0197)	TÜV Rheinland LGA Products GmbH (0197)	2028-12-31	N/A
Veraviewepocs	HD 60147054 0001	2024-05-26	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	N/A
Veraview iX	HD 60147054 0001	2024-05-26	TÜV Rheinland LGA Products GmbH (0197)	TÜV Rheinland LGA Products GmbH (0197)	2028-12-31	N/A

CONFIDENTIAL

MORITA

EC DECLARATION OF CONFORMITY

Here we,

J. MORITA MFG. CORP.

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

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

declare under own responsibility, that the product;

Kind of Product:	**Endodontic Treatment Motorized Handpiece**
Product Name:	**Tri Auto mini / Rooter S / Endostar Provider**
Model:	**TR-CM**
Type:	-
Medical Product Class:	**Class IIa as Rule 9**
UMDNS Code:	**16-411 (Broaches, Root Canal)**

is in compliance with the European Directive,

93/42/EEC

Counsil 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 has been approved by the following notified body:

Notified Body:

TÜV Rheinland LGA Products GmbH

Tillystrasse 2, 90431, Nuremberg, Germany

Identification No. 0197

Registration No.: HD 60147054 0001

EU Authorized Representative:

Medical Technology Promedt Consulting

Altenhofstrasse 80, 66386 St. Ingbert, Germany

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

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Kyoto, Japan

Place

Date 2020.12.2

Yoshihiko Takashima

Yoshihiko Takashima

Managing Director