

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.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

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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

Date: 2020-04-20


Takashi Matsuda

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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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

Date: 2020-04-20



Notified Body


Takashi Matsuda