

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

**Registration No.:** HD 60075668 0001

**Report No.:** 12018176 001

**Manufacturer:** J. MORITA MFG. CORP.  
680 Higashihama Minami-cho, Fushimi-ku  
KYOTO, 612-8533  
JAPAN

**Products:** Design/Development and Manufacture of Electrical and  
Air Driven Equipment for Dentistry and Diagnostic Imaging  
  
(see attachment for products and additional sites included)  
  
Replaces Approval, Registration No.: HD 60029478 0001

**Expiry Date:** 2017-05-22

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:** 2012-05-23

**Date:** 2012-05-23



Notified Body

  
Dipl.-Ing. O. Masur

**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 60075668 0001  
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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

**Date:** 2012-05-23



**Notified Body**

  
**Dipl.-Ing. O. Masur**

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

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KYOTO, 612-8533  
JAPAN

Products and additional Sites included:

J. MORITA MFG CORP.  
Kumiyama Factory  
190 Koaza Shintamaki, Ooaza Ichida, Kumiyama-cho  
Kuse-gun, Kyoto, 613-0022, Japan

Scope: Manufacture of Electrical and Air Driven  
Equipment for Dentistry and Diagnostic Imaging

Product:  
Dental treatment units

**Date:** 2012-05-23



**Notified Body**

  
**Dipl.-Ing. O. Masur**