

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

**Registration No.:** HD 60134044 0001

**Report No.:** 12022660 007

**Manufacturer:** Nemoto Kyorindo Co., Ltd.  
2-27-20 Hongo, Bunkyo-ku  
Tokyo 113-0033  
Japan

**Products:** CT Contrast Delivery Systems, MR Contrast Delivery Systems,  
Angiography Contrast Delivery Systems, Extravasation Sensors  
  
(see attachment for sites included)

Replaces Approval, Registration No.: HD 60103647 0001

**Expiry Date:** 2023-11-07

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:** 2018-11-08

**Date:** 2018-11-07



Notified Body

*M. Aihara*  
M.Sc. M. Aihara

**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 60134044 0001  
**Report No.:** 12022660 007

**Manufacturer:** Nemoto Kyorindo Co., Ltd.  
2-27-20 Hongo, Bunkyo-ku  
Tokyo 113-0033  
Japan

Sites included :

Nemoto Kyorindo Co., Ltd.  
Test site  
1-4-18 Asahi, Kawaguchi-shi, Saitama 332-0001, Japan  
Manufacture

Nemoto Kyorindo Co., Ltd.  
Kawaguchi Plant  
2-12-23 Aoki, Kawaguchi-shi, Saitama 332-0031, Japan  
Manufacture

Nemoto Kyorindo Co., Ltd.  
Technical Center  
2-12-4 Aoki, Kawaguchi-shi, Saitama 332-0031, Japan  
Design/ development

Nemoto Kyorindo Co., Ltd.  
Kawaguchi Warehouse  
1-7-5 Asahi, Kawaguchi-shi, Saitama 332-0001, Japan  
Manufacture

**Date:** 2018-11-07



**Notified Body**

*M. Aihara*  
**M.Sc. M. Aihara**