

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