

CERTIFICATE

I hereby certify that the attached documents are true and correct.

November 21, 2016
Nemoto Kyorindo Co., Ltd.
Overseas Department



Sachiko Sugimoto



Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

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

has established and applies a quality management system for medical devices
for the following scope:

**Design and Development, Manufacture and Distribution of
CT Contrast Delivery Systems, MR Contrast Delivery Systems,
Angiography Contrast Delivery Systems and
Extravasation Sensors**

Proof has been furnished that the requirements specified in

EN ISO 13485:2012
EN ISO 13485:2012/AC:2012


are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2016-11-04
Certificate Registration No.: SX 60114588 0001
An audit was performed. Report No.: 12031304 001
This Certificate is valid until: 2019-03-30

Certification Body



Date 2016-11-04


M.Sc. M. Aihara

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com http://www.tuv.com/safety



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/3, Rev. 0

**Attachment to
 Certificate**

Registration No.: SX 60114588 0001
Report No.: 12031304 001

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

Scope:

Sites included:

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

Scope:
 Distribution of CT Contrast Delivery Systems,
 MR Contrast Delivery Systems, Angiography Contrast Delivery
 Systems and Extravasation Sensors

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

Scope:
 Manufacture, Purchasing, Inspection and Quality Assurance
 of CT Contrast Delivery Systems, MR Contrast Delivery
 Systems, Angiography Contrast Delivery Systems and
 Extravasation Sensors

Certification Body



M. Aihara

Date: 2016-11-04

M.Sc. M. Aihara



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 2/3, Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60114588 0001
Report No.: 12031304 001

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

Scope:

Sites included:

Nemoto Kyorindo Co., Ltd.
Kawaguchi 2nd Plant
2-12-24 Aoki, Kawaguchi-shi, Saitama, 332-0031, Japan

Scope:

Incoming Inspection and Manufacturing of CT Contrast Delivery Systems, MR Contrast Delivery Systems, Angiography Contrast Delivery Systems and Extravasation Sensors

Nemoto Kyorindo Co., Ltd.

Technical Center

2-12-4 Aoki, Kawaguchi-shi, Saitama 332-0031, Japan

Scope:

Design and development of CT Contrast Delivery Systems, MR Contrast Delivery Systems, Angiography Contrast Delivery Systems and Extravasation Sensors

Certification Body



Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02



M. Aihara

M.Sc. M. Aihara

Date: 2016-11-04



Doc. 3/3, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60114588 0001
Report No.: 12031304 001

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

Scope:

Sites included:

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

Scope:

Storage for the parts of CT Contrast Delivery Systems,
MR Contrast Delivery Systems, Angiography Contrast
Delivery Systems and Extravasation Sensors

Certification Body



Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02



M. Aihara

M.Sc. M. Aihara

Date: 2016-11-04



囑託人 杉本 幸子 は、別紙編綴の書面に署名したことを自認する旨、
本公証人の面前で陳述した。

よって、これを認証する。

平成28年 11月 22日、本公証人役場において
東京都文京区春日1丁目16番21号

東京法務局所属

公 証 人
Notary
Masaki Sasaki

佐：杉本幸子
証 明

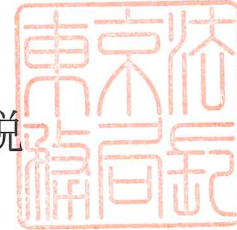


上記署名は、東京法務局所属公証人の署名に相違ないものであり、かつ、その押印は、
真実のものであることを証明する。

平成28年 11 月 22 日

東京法務局長

佐藤 主 税



APOSTILLE

(Convention de La Haye du 5 octobre 1961)

- 1. Country: JAPAN
This public document
- 2. has been signed by Masaki Sasaki
- 3. acting in the capacity of Notary of the Tokyo Legal Affairs Bureau
- 4. bears the seal/stamp of Masaki Sasaki, Notary
Certified
- 5. at Tokyo
- 6. NOV, 22, 2016
- 7. by the Ministry of Foreign Affairs
- 8. 16-N~~0~~065600
- 9. Seal/stamp:
- 10. Signature



A. Ogawa

Ayako OGAWA

For the Minister for Foreign Affairs



Registered No. 763 of 2016

NOTARIAL CERTIFICATE

This is to certify that Sachiko Sugimoto acknowledged that the signature on the attached document is her own on this 22th day of November, 2016.

NOTARY

Masaki Sasaki

Notary, Bunkyo Notary's Office

Tokyo Legal Affairs Bureau,

1 - 16 - 21 Kasuga, Bunkyo - Ku, Tokyo