

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that: Nemoto Kyorindo Co., Ltd.  
2-27-20 Hongo,  
Bunkyo-ku,  
Tokyo  
113-0033  
Japan

株式会社 根本杏林堂  
〒113-0033  
東京都  
文京区  
本郷2-27-20

Holds Certificate No: MD 767755

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

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

CT 用造影剤注入装置、MR 用造影剤注入装置、アンギオグラフィ用造影剤注入装置および血管外漏れセンサーの設計・開発、製造、販売、設置およびサービス

Transfer from TUV Rheinland Register Certificate Identity number: SX 60143975 0001

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2022-04-05

Latest Revision Date: 2022-08-05

Effective Date: 2022-11-08

Expiry Date: 2025-11-07

Page: 1 of 3



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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000  
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
A Member of the BSI Group of Companies.

Certificate No: MD 767755

Location	Registered Activities
Nemoto Kyorindo Co., Ltd. 2-27-20 Hongo, Bunkyo-ku, Tokyo 113-0033 Japan 株式会社 根本杏林堂 〒113-0033 東京都 文京区 本郷2-27-20	Distribution of CT Contrast Delivery Systems, MR Contrast Delivery Systems, Angiography Contrast Delivery Systems and Extravasation Sensors CT 用造影剤注入装置、MR 用造影剤注入装置、アンギオグラフィ用造影剤注入装置および血管外漏れセンサーの販売
Nemoto Kyorindo Co., Ltd. Kawaguchi Plant 2-12-23 Aoki, Kawaguchi-shi, Saitama 332-0031 Japan 株式会社 根本杏林堂 川口工場 〒332-0031 埼玉県 川口市 青木2-12-23	Manufacture of CT Contrast Delivery Systems, MR Contrast Delivery Systems, Angiography Contrast Delivery Systems and Extravasation Sensors CT 用造影剤注入装置、MR 用造影剤注入装置、アンギオグラフィ用造影剤注入装置および血管外漏れセンサーの製造
Nemoto Kyorindo Co., Ltd. Technical Center 2-12-4 Aoki, Kawaguchi-shi, Saitama 332-0031 Japan 株式会社 根本杏林堂 技術センター 〒332-0031 埼玉県 川口市 青木2-12-4	Design and Development of CT Contrast Delivery Systems, MR Contrast Delivery Systems, Angiography Contrast Delivery Systems and Extravasation Sensors CT 用造影剤注入装置、MR 用造影剤注入装置、アンギオグラフィ用造影剤注入装置および血管外漏れセンサーの設計開発

Original Registration Date: 2022-04-05

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Page: 2 of 3

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Location	Registered Activities
Nemoto Kyorindo Co., Ltd. Test Site 1-4-18, Asahi, Kawaguchi-shi, Saitama 332-0001 Japan 株式会社 根本杏林堂 テストサイト 〒332-0001 埼玉県 川口市 朝日1-4-18	Installation and Service of CT Contrast Delivery Systems, MR Contrast Delivery Systems, Angiography Contrast Delivery Systems and Extravasation Sensors CT 用造影剤注入装置、MR 用造影剤注入装置、アンギオグラフィ用造影剤注入装置および血管外漏れセンサーの付帯サービス
Nemoto Kyorindo Co., Ltd. Kawaguchi Warehouse 1-7-5, Asahi, Kawaguchi-shi, Saitama 332-0001 Japan 株式会社 根本杏林堂 川口倉庫 〒332-0001 埼玉県 川口市 朝日1-7-5	Storage of components of CT Contrast Delivery Systems, MR Contrast Delivery Systems, Angiography Contrast Delivery Systems and Extravasation Sensors CT 用造影剤注入装置、MR 用造影剤注入装置、アンギオグラフィ用造影剤注入装置および血管外漏れセンサーの部品の保管

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Page: 3 of 3

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