

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**Shimadzu Corporation
Medical Systems Division
1, Nishinokyo-Kuwabaracho
Nakagyo-ku, Kyoto
604-8511 Japan**

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

**In accordance with EN ISO 13485:2016 Medical devices
-Quality management systems-Requirements for regulatory
purposes (ISO 13485:2016)
See attachment(s) for the scope**

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

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

Effective Date: 2020-02-26
Certificate Registration No.: SX 60146920 0001
An audit was performed. Report No.: 12031273 014
This Certificate is valid until: 2022-05-12

Certification Body



Date 2020-02-26




Masahiro Asami

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. 1/20, Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60146920 0001
Report No.: 12031273 014

Organization: Shimadzu Corporation
Medical Systems Division
1, Nishinokyo-Kuwabaracho
Nakagyo-ku, Kyoto
604-8511 Japan

Scope:

Design and Development, Manufacture, Importing and
Distribution of Medical Diagnostic Imaging Devices and
Systems,

Product group and full product description:

Nuclear Magnetic Resonance Imaging Systems, X-Ray Computer
Tomography Devices, Diagnostic X-Ray Devices, Angiographic
X-Ray Diagnostic Systems, Diagnostic Ultrasound Systems,
X-Ray Tube Assemblies, Image Intensifiers, Nuclear Medicine
Diagnostic Devices, Medical Image Management Systems,
General Health Management Systems, Oximeter, Computer Aided
Detection System, Accelerator System Synchronizer,
Near Infrared Fluorescence Imaging System,
Work Station Software for Diagnostic X-Ray Systems

Certification Body



Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02



Date: 2020-02-26



Masahiro Asami

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 2/20, Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60146920 0001
Report No.: 12031273 014

Organization: Shimadzu Corporation
Medical Systems Division
1, Nishinokyo-Kuwabaracho
Nakagyo-ku, Kyoto
604-8511 Japan

Scope:

Sites included:

Shimadzu Corporation, Medical Systems Division
1, Nishinokyo-Kuwabaracho, Nakagyo-ku, Kyoto 604-8511, Japan

Scope:

Design and Development, Manufacture, Importing and
Distribution of Medical Diagnostic Imaging Devices and
Systems.

Product group and full product description:

Nuclear Magnetic Resonance Imaging Systems, X-Ray Computer
Tomography Devices, Diagnostic X-Ray Devices, Angiographic
X-Ray Diagnostic Systems, Diagnostic Ultrasound Systems,
X-Ray Tube Assemblies, Image Intensifiers, Nuclear Medicine
Diagnostic Devices, Medical Image Management Systems,
General Health Management Systems, Oximeter, Computer Aided
Detection System, Accelerator System Synchronizer,
Near Infrared Fluorescence Imaging System,
Work Station Software for Diagnostic X-Ray Systems

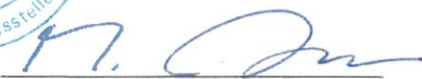
Certification Body



Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02



Date: 2020-02-26


Masahiro Asami

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 3/20, Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60146920 0001
Report No.: 12031273 014

Organization: Shimadzu Corporation
Medical Systems Division
1, Nishinokyo-Kuwabaracho
Nakagyo-ku, Kyoto
604-8511 Japan

Scope:

Sites included:

Shimadzu Corporation, Sanjo Works
(Shimadzu Corporation, Sanjo Factory)
1, Nishinokyo-Kuwabaracho, Nakagyo-ku, Kyoto 604-8511, Japan

Scope:

Design and Development, Manufacture, Importing and
Distribution of Medical Diagnostic Imaging Devices and
Systems

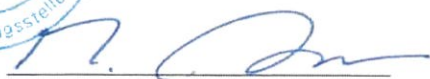
Product group and full productdescription:

Nuclear Magnetic Resonance Imaging Systems, X-Ray Computer
Tomography Devices, Diagnostic X-Ray Devices, Angiographic
X-Ray Diagnostic Systems, Diagnostic Ultrasound Systems,
X-Ray Tube Assemblies, Image Intensifiers, Nuclear Medicine
Diagnostic Devices, Medical Image Management Systems,
General Health Management Systems, Oximeter, Computer Aided
Detection System, Accelerator System Synchronizer,
Near Infrared Fluorescence Imaging System,
Work Station Software for Diagnostic X-Ray Systems

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Date: 2020-02-26


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LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60146920 0001
Report No.: 12031273 014

Organization: Shimadzu Corporation
Medical Systems Division
1, Nishinokyo-Kuwabaracho
Nakagyo-ku, Kyoto
604-8511 Japan

Scope:

Sites included:
Sales Planning Section
1-3 Kanda-Nishiki-cho, Chiyoda-ku, Tokyo 101-8448, Japan
Scope:

Distribution of Medical Diagnostic Imaging Devices and
Systems

Promotion section for Cardiac Vascular System
1-3 Kanda-Nishiki-cho, Chiyoda-ku, Tokyo 101-8448, Japan
Scope:

Distribution of Medical Diagnostic Imaging Devices and
Systems

National Sales Channel Management Section
1-3 Kanda-Nishiki-cho, Chiyoda-ku, Tokyo 101-8448, Japan
Scope:

Distribution of Medical Diagnostic Imaging Devices and
Systems

Certification Body



Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02



Date: 2020-02-26


Masahiro Asami

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 5/20, Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60146920 0001
Report No.: 12031273 014

Organization: Shimadzu Corporation
Medical Systems Division
1, Nishinokyo-Kuwabaracho
Nakagyo-ku, Kyoto
604-8511 Japan

Scope:

Sites included:

Sapporo Office Medical Systems, Sales Section
Sapporo Kita Building, 9F, Kita 7-jo, Nishi 2-chome 8-1,
Kita-ku, Sapporo-shi, Hokkaido 060-0807, Japan

Scope:

Distribution of Medical Diagnostic Imaging Devices and
Systems

Tohoku Office Medical Systems, Sales Section

Prime Square Hirose-dori Bldg. 12F, Chuo 2-9-27, Aoba-ku,
Sendai-shi, Miyagi 980-0021, Japan

Scope:

Distribution of Medical Diagnostic Imaging Devices and
Systems

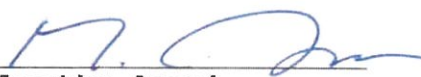
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Deutsche
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D-ZM-14169-01-02



Date: 2020-02-26



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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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**Attachment to
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Registration No.: SX 60146920 0001
Report No.: 12031273 014

Organization: Shimadzu Corporation
Medical Systems Division
1, Nishinokyo-Kuwabaracho
Nakagyo-ku, Kyoto
604-8511 Japan

Scope:

Sites included:
Akita Sales Office
Toda Bldg. 2-25, Higashidori Nakamachi, Akita-shi, Akita
010-0002, Japan

Scope:
Distribution of Medical Diagnostic Imaging Devices and
Systems

Koriyama Sales Office
Koriyama Fukoku Seimei Bldg. 2F, 6-7 Domaecho, Koriyama-shi,
Fukushima 963-8877, Japan

Scope:
Distribution of Medical Diagnostic Imaging Devices and
Systems

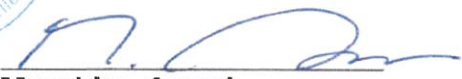
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Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02



Date: 2020-02-26


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LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 7/20, Rev. 0

**Attachment to
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Registration No.: SX 60146920 0001
Report No.: 12031273 014

Organization: Shimadzu Corporation
Medical Systems Division
1, Nishinokyo-Kuwabaracho
Nakagyo-ku, Kyoto
604-8511 Japan

Scope:

Sites included:

Tokyo Office Medical Systems, Sales Section
1-3 Kanda-Nishiki-cho, Chiyoda-ku, Tokyo 101-8448, Japan

Scope:

Distribution of Medical Diagnostic Imaging Devices and
Systems

Chiba Sales Office

Daiso Center Bldg. 3F, 2-7-2 Shinchiba, Chuo-ku, Chiba-shi,
Chiba 260-0031, Japan

Scope:

Distribution of Medical Diagnostic Imaging Devices and
Systems

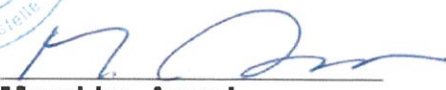
Certification Body



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D-ZM-14169-01-02



Date: 2020-02-26


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**Attachment to
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Registration No.: SX 60146920 0001
Report No.: 12031273 014

Organization: Shimadzu Corporation
Medical Systems Division
1, Nishinokyo-Kuwabaracho
Nakagyo-ku, Kyoto
604-8511 Japan

Scope:

Sites included:
Yamanashi Sales Office
Green Heights Tachibana 101, 2-4-10 Sumiyoshi, Kofu-shi,
Yamanashi 400-0851, Japan

Scope:
Distribution of Medical Diagnostic Imaging Devices and
Systems

Yokohama Office Medical Systems, Sales Section
Tobu-Yokohama No.3 Bldg. 7F, 2-8-29 Kita-Saiwai, Nishi-ku,
Yokohama-shi, Kanagawa 220-0004, Japan

Scope:
Distribution of Medical Diagnostic Imaging Devices and
Systems

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Registration No.: SX 60146920 0001
Report No.: 12031273 014

Organization: Shimadzu Corporation
Medical Systems Division
1, Nishinokyo-Kuwabaracho
Nakagyo-ku, Kyoto
604-8511 Japan

Scope:

Sites included:

Nagoya Office Medical Systems, Sales Section:
Nagoya Kokusai Center Bldg. 19F, 1-47-1 Nagono, Nakamura-ku,
Nagoya-shi, Aichi 450-0001, Japan

Scope:

Distribution of Medical Diagnostic Imaging Devices and
Systems

Kyoto Office Medical Systems, Sales Section:

1 Nishinokyo-Tokudaijicho, Nakagyo-ku, Kyoto-shi, Kyoto
604-8445, Japan

Scope:

Distribution of Medical Diagnostic Imaging Devices and
Systems

Certification Body



Deutsche
Akkreditierungsstelle
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TÜV Rheinland
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Tillystraße 2, 90431 Nürnberg

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**Attachment to
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Registration No.: SX 60146920 0001
Report No.: 12031273 014

Organization: Shimadzu Corporation
Medical Systems Division
1, Nishinokyo-Kuwabaracho
Nakagyo-ku, Kyoto
604-8511 Japan

Scope:

Sites included:
Shiga Sales Office
Daini-Kojima Bldg. 1F, 300-21 Fuke-Cho, Moriyama-shi, Shiga
524-0033, Japan

Scope:
Distribution of Medical Diagnostic Imaging Devices and
Systems

Kansai Office Medical Systems, Sales Section:
Hankyu Terminal Bldg. 14F, 1-1-4 Shibata, Kita-ku,
Osaka-shi, Osaka 530-0012, Japan

Scope:
Distribution of Medical Diagnostic Imaging Devices and
Systems

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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**Attachment to
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Registration No.: SX 60146920 0001
Report No.: 12031273 014

Organization: Shimadzu Corporation
Medical Systems Division
1, Nishinokyo-Kuwabaracho
Nakagyo-ku, Kyoto
604-8511 Japan

Scope:

Sites included:
Kobe Sales Office
Eikoh Bldg. 9F, 93 Edo-machi, Chuo-ku, Kobe-shi, Hyogo
650-0033, Japan
Scope:
Distribution of Medical Diagnostic Imaging Devices and
Systems

Nara Sales Office
Nissei Naraekimae Bldg. 4F, 1-1-15 Omiyacho, Nara-shi, Nara
630-8115, Japan
Scope:
Distribution of Medical Diagnostic Imaging Devices and
Systems

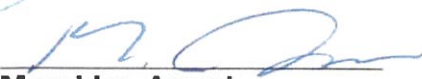
Certification Body



Deutsche
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D-ZM-14169-01-02



Date: 2020-02-26



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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 12/20, Rev. 0

**Attachment to
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Report No.: 12031273 014

Organization: Shimadzu Corporation
Medical Systems Division
1, Nishinokyo-Kuwabaracho
Nakagyo-ku, Kyoto
604-8511 Japan

Scope:

Sites included:

Okayama Sales Office

Sumitomo Seimei Okayama Newcity Bldg. 6F, 3-10 Togyacho,
Kita-ku, Okayama-shi, Okayama 700-0826, Japan

Scope:

Distribution of Medical Diagnostic Imaging Devices and
Systems

Tottori Sales Office

6-1-32 Shinkai, Yonago-shi, Tottori 683-0801, Japan

Scope:

Distribution of Medical Diagnostic Imaging Devices and
Systems

Certification Body



Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02



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LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 13/20, Rev. 0

**Attachment to
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Registration No.: SX 60146920 0001
Report No.: 12031273 014

Organization: Shimadzu Corporation
Medical Systems Division
1, Nishinokyo-Kuwabaracho
Nakagyo-ku, Kyoto
604-8511 Japan

Scope:

Sites included:
Hiroshima Office Medical Systems, Sales Section
Meiji Yasuda Seimei Hiroshima Bldg. 15F, 4-25 Fukuro-machi,
Naka-ku, Hiroshima-shi, Hiroshima 732-0036, Japan

Scope:
Distribution of Medical Diagnostic Imaging Devices and
Systems

Yamaguchi Sales Office
5-18 Ogoriminamimachi, Yamaguchi-shi, Yamaguchi
754-0013, Japan

Scope:
Distribution of Medical Diagnostic Imaging Devices and
Systems

Certification Body



Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02



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Masahiro Asami

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 14/20, Rev. 0

**Attachment to
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Registration No.: SX 60146920 0001
Report No.: 12031273 014

Organization: Shimadzu Corporation
Medical Systems Division
1, Nishinokyo-Kuwabaracho
Nakagyo-ku, Kyoto
604-8511 Japan

Scope:

Sites included:
Shimane Sales Office
2698 Naoe, Hikawacho, Izumo-shi, Shimane 699-0631, Japan

Scope:
Distribution of Medical Diagnostic Imaging Devices and
Systems

Shikoku Office Medical Systems, Sales Section
Takamatsu NK Bldg. 9F, 1-6-1 Ban-cho, Takamatsu-shi, Kagawa
760-0017, Japan

Scope:
Distribution of Medical Diagnostic Imaging Devices and
Systems

Certification Body



Date: 2020-02-26



Masahiro Asami

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 15/20, Rev. 0

**Attachment to
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Report No.: 12031273 014

Organization: Shimadzu Corporation
Medical Systems Division
1, Nishinokyo-Kuwabaracho
Nakagyo-ku, Kyoto
604-8511 Japan

Scope:

Sites included:

Matsuyama Sales Office

Pure Dogo 1F, 5-48 Dogoimaichi, Matsuyama-shi, Ehime
790-0845, Japan

Scope:

Distribution of Medical Diagnostic Imaging Devices and
Systems

Tokushima Sales Office

6-7-2 Sumiyoshi, Tokushima-shi, Tokushima 770-0861, Japan

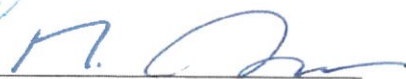
Scope:

Distribution of Medical Diagnostic Imaging Devices and
Systems

Certification Body



Date: 2020-02-26


Masahiro Asami

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 16/20, Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60146920 0001
Report No.: 12031273 014

Organization: Shimadzu Corporation
Medical Systems Division
1, Nishinokyo-Kuwabaracho
Nakagyo-ku, Kyoto
604-8511 Japan

Scope:

Sites included:

Kochi Sales Office

Seiry Heights, 1-4-17 Chiyoricho, Kochi-shi, Kochi
780-0806, Japan

Scope:

Distribution of Medical Diagnostic Imaging Devices and
Systems

Kyushu Office Medical Systems, Sales Section

Shimadzu Hakata Bldg. 4F, 4-20 Reisen-machi, Hakata-ku,
Fukuoka-shi, Fukuoka 812-0039, Japan

Scope:

Distribution of Medical Diagnostic Imaging Devices and
Systems

Certification Body



DAkkS

Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02



Date: 2020-02-26



Masahiro Asami

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 17/20, Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60146920 0001
Report No.: 12031273 014

Organization: Shimadzu Corporation
Medical Systems Division
1, Nishinokyo-Kuwabaracho
Nakagyo-ku, Kyoto
604-8511 Japan

Scope:

Sites included:
Kita-Kyusyu Sales Office
2-8-11 Katanoshinmachi, Kokurakita-ku, Kitakyusyu-shi,
Fukuoka 802-0062, Japan

Scope:
Distribution of Medical Diagnostic Imaging Devices and
Systems

Tosu Sales Office
1311-8 Motomachi, Tosu-shi, Saga 841-0051, Japan

Scope:
Distribution of Medical Diagnostic Imaging Devices and
Systems

Certification Body



Date: 2020-02-26



Masahiro Asami

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 18/20, Rev. 0

**Attachment to
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Registration No.: SX 60146920 0001
Report No.: 12031273 014

Organization: Shimadzu Corporation
Medical Systems Division
1, Nishinokyo-Kuwabaracho
Nakagyo-ku, Kyoto
604-8511 Japan

Scope:

Sites included:
Oita Sales Office
176-1 Houjyo, Oita-shi, Oita 870-0055, Japan
Scope:
Distribution of Medical Diagnostic Imaging Devices and
Systems

Nagasaki Sales Office
Sensyu Daini Bldg. 6-32, Chitosemachi, Nagasaki-shi,
Nagasaki 852-8135, Japan
Scope:
Distribution of Medical Diagnostic Imaging Devices and
Systems

Certification Body



Date: 2020-02-26


Masahiro Asami

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 19/20, Rev. 0

**Attachment to
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Registration No.: SX 60146920 0001
Report No.: 12031273 014

Organization: Shimadzu Corporation
Medical Systems Division
1, Nishinokyo-Kuwabaracho
Nakagyo-ku, Kyoto
604-8511 Japan

Scope: Sites included:
Miyazaki Sales Office
952-1 Tsunehisa, Miyazaki-shi, Miyazaki 880-0916, Japan
Scope:
Distribution of Medical Diagnostic Imaging Devices and
Systems

Kagoshima Sales Office
1-33-1 Higashitaniyama, Kagoshima-shi, Kagoshima
891-0113, Japan
Scope:
Distribution of Medical Diagnostic Imaging Devices and
Systems

Certification Body



Date: 2020-02-26



Masahiro Asami

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 20/20, Rev. 0

**Attachment to
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Registration No.: SX 60146920 0001
Report No.: 12031273 014

Organization: Shimadzu Corporation
Medical Systems Division
1, Nishinokyo-Kuwabaracho
Nakagyo-ku, Kyoto
604-8511 Japan

Scope:

Sites included:
Kumamoto Sales Office
2-20-45 Hirata, Kumamoto-shi, Kumamoto 860-0826, Japan

Scope:
Distribution of Medical Diagnostic Imaging Devices and
Systems

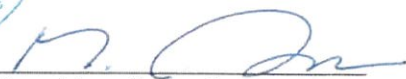
International Operations Department
1-3 Kanda-Nishiki-cho, Chiyoda-ku, Tokyo 101-8448, Japan

Scope:
Distribution of Medical Diagnostic Imaging Devices and
Systems

Certification Body



Date: 2020-02-26


Masahiro Asami