

Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 2365675-1

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

Scope: Design, Development, Manufacture, Importing, Distribution, Servicing and Administration of Medical Diagnostic Imaging Devices and Systems
Product group and full product description:
Diagnostic X-Ray Devices, Angiographic X-Ray Diagnostic 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

Manufacture, Distribution, Servicing and Administration of Medical Diagnostic Imaging Devices and Systems
Product group and full product description:
Nuclear Magnetic Resonance Imaging Systems, X-Ray Computer Tomography Devices and Diagnostic Ultrasound Systems

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 150274490-301, 150256590-301
Effective date: 2023-05-13
Expiry date: 2025-05-12
Issue date: 2023-05-08



Michiaki Aihara

Michiaki Aihara
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany



Certificate

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Medical Systems Division
1, Nishinokyo-Kuwabaracho,
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604-8511 Japan

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o Shimadzu Corporation, Medical Systems Division 1, Nishinokyo-Kuwabaracho, Nakagyo-ku Kyoto 604-8511 Japan	<p>Design, Development, Manufacture, Importing, Distribution and Servicing of Medical Diagnostic Imaging Devices and Systems</p> <p>Product group and full product description: Diagnostic X-Ray Devices, Angiographic X-Ray Diagnostic 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</p> <p>Manufacture, Distribution and Servicing of Medical Diagnostic Imaging Devices and Systems</p> <p>Product group and full product description: Nuclear Magnetic Resonance Imaging Systems, X-Ray Computer Tomography Devices and Diagnostic Ultrasound Systems</p>

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1, Nishinokyo-Kuwabaracho,
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604-8511 Japan

The scope of certification also covers the following:

/02 c/o Shimadzu Corporation,
Sanjo Works (Shimadzu
Corporation, Sanjo Factory)
1, Nishinokyo-Kuwabaracho
Nakagyo-ku, Kyoto
604-8511 Japan

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

Product group and full product description:
Diagnostic X-Ray Devices, Angiographic X-Ray
Diagnostic 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

Manufacture, Distribution and Servicing of Medical
Diagnostic Imaging Devices and Systems

Product group and full product description:
Nuclear Magnetic Resonance Imaging Systems,
X-Ray Computer Tomography Devices and
Diagnostic Ultrasound Systems

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1, Nishinokyo-Kuwabaracho,
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604-8511 Japan

The scope of certification also covers the following:

- | | | |
|-----|---|---|
| /03 | c/o Shimadzu Corporation
Sales Planning Section
1-3 Kanda-Nishiki-cho,
Chiyoda-ku, Tokyo
101-8448 Japan | Distribution of Medical Diagnostic Imaging
Devices and Systems |
| /04 | c/o Shimadzu Corporation
Future Healthcare Enhancement Group
1-3 Kanda-Nishiki-cho,
Chiyoda-ku, Tokyo
101-8448 Japan | Distribution of Medical Diagnostic Imaging
Devices and Systems |
| /05 | c/o Shimadzu Corporation
Promotion section for Cardiac Vascular
System
1-3 Kanda-Nishiki-cho,
Chiyoda-ku, Tokyo
101-8448 Japan | Distribution of Medical Diagnostic Imaging
Devices and Systems |
| /06 | c/o Shimadzu Corporation
National Sales Channel Management
Section
1-3 Kanda-Nishiki-cho,
Chiyoda-ku, Tokyo
101-8448 Japan | Distribution of Medical Diagnostic Imaging
Devices and Systems |

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604-8511 Japan

The scope of certification also covers the following:

- | | | |
|-----|---|---|
| /07 | c/o Shimadzu Corporation
Sapporo Office Medical Systems,
Sales Section
Sapporo Kita Bldg. 9F,
Kita 7-jo, Nishi 2-chome 8-1,
Kita-ku, Sapporo-shi, Hokkaido
060-0807 Japan | Distribution of Medical Diagnostic Imaging
Devices and Systems |
| /08 | c/o Shimadzu Corporation
Tohoku Office Medical Systems,
Sales Section
Prime Square Hirose-dori Bldg.
12F, Chuo 2-9-27,
Aoba-ku, Sendai-shi, Miyagi
980-0021 Japan | Distribution of Medical Diagnostic Imaging
Devices and Systems |
| /09 | c/o Shimadzu Corporation
Akita Sales Office
Toda Bldg.
2-25, Higashidori Nakamachi,
Akita-shi, Akita
010-0002 Japan | Distribution of Medical Diagnostic Imaging
Devices and Systems |

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1, Nishinokyo-Kuwabaracho,
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604-8511 Japan

The scope of certification also covers the following:

- | | | |
|-----|---|---|
| /10 | c/o Shimadzu Corporation
Koriyama Sales Office
Koriyama Fukoku Seimei Bldg. 2F,
6-7 Domaecho,
Koriyama-shi, Fukushima
963-8877 Japan | Distribution of Medical Diagnostic Imaging
Devices and Systems |
| /11 | c/o Shimadzu Corporation
Tokyo Office Medical Systems,
Sales Section
1-3 Kanda-Nishiki-cho,
Chiyoda-ku, Tokyo
101-8448 Japan | Distribution of Medical Diagnostic Imaging
Devices and Systems |
| /12 | c/o Shimadzu Corporation
Chiba Sales Office
Daiso Center Bldg. 3F,
2-7-2 Shinchiba, Chuo-ku,
Chiba-shi, Chiba
260-0031 Japan | Distribution of Medical Diagnostic Imaging
Devices and Systems |

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604-8511 Japan

The scope of certification also covers the following:

- | | | |
|-----|--|---|
| /13 | c/o Shimadzu Corporation
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 | Distribution of Medical Diagnostic Imaging
Devices and Systems |
| /14 | c/o Shimadzu Corporation
Nagoya Office Medical Systems,
Sales Section
Nagoya Kokusai Center Bldg. 19F
1-47-1 Nagono, Nakamura-ku,
Nagoya-shi, Aichi
450-0001 Japan | Distribution of Medical Diagnostic Imaging
Devices and Systems |
| /15 | c/o Shimadzu Corporation
Kyoto Office Medical Systems,
Sales Section
1 Nishinokyo-Tokudaijicho
Nakagyo-ku, Kyoto-shi, Kyoto
604-8445 Japan | Distribution of Medical Diagnostic Imaging
Devices and Systems |

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1, Nishinokyo-Kuwabaracho,
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604-8511 Japan

The scope of certification also covers the following:

- | | | |
|-----|---|---|
| /16 | c/o Shimadzu Corporation
Shiga Sales Office
Daini-Kojima Bldg. 1F,
300-21 Fuke-Cho,
Moriyama-shi, Shiga
524-0033 Japan | Distribution of Medical Diagnostic Imaging
Devices and Systems |
| /17 | c/o Shimadzu Corporation
Kansai Office Medical Systems,
Sales Section
Hankyu Terminal Bldg. 14F,
1-1-4 Shibata, Kita-ku, Osaka-shi, Osaka
530-0012 Japan | Distribution of Medical Diagnostic Imaging
Devices and Systems |
| /18 | c/o Shimadzu Corporation
Kobe Sales Office:
Eikoh Bldg. 9F, 93 Edo-machi,
Chuo-ku, Kobe-shi, Hyogo
650-0033 Japan | Distribution of Medical Diagnostic Imaging
Devices and Systems |

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The scope of certification also covers the following:

- | | | |
|-----|---|---|
| /19 | c/o Shimadzu Corporation
Nara Sales Office
Nissei Naraekimae Bldg. 4F,
1-1-15 Omiyacho,
Nara-shi, Nara
630-8115 Japan | Distribution of Medical Diagnostic Imaging
Devices and Systems |
| /20 | c/o Shimadzu Corporation
Okayama Sales Office
Sumitomo Seimei Okayama New City
Building, 6F, 3-10 Togyacho,
Kita-ku, Okayama-shi, Okayama
700-0826 Japan | Distribution of Medical Diagnostic Imaging
Devices and Systems |
| /21 | c/o Shimadzu Corporation
Tottori Sales Office
6-1-32 Shinkai,
Yonago-shi, Tottori
683-0801 Japan | Distribution of Medical Diagnostic Imaging
Devices and Systems |

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604-8511 Japan

The scope of certification also covers the following:

- | | | |
|-----|--|---|
| /22 | c/o Shimadzu Corporation
Hiroshima Office Medical Systems,
Sales Section
GRANODE Hiroshima Building, 5F,
3-5-7 Futabanosato, Higashi-ku,
Hiroshima-shi, Hiroshima
732-0057 Japan | Distribution of Medical Diagnostic Imaging
Devices and Systems |
| /23 | c/o Shimadzu Corporation
Yamaguchi Sales Office
5-18 Ogoriminamimachi,
Yamaguchi-shi, Yamaguchi
754-0013 Japan | Distribution of Medical Diagnostic Imaging
Devices and Systems |
| /24 | c/o Shimadzu Corporation
Shimane Sales Office
2698 Naoe, Hikawacho,
Izumo-shi, Shimane
699-0631 Japan | Distribution of Medical Diagnostic Imaging
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604-8511 Japan

The scope of certification also covers the following:

- | | | |
|-----|---|---|
| /25 | c/o Shimadzu Corporation
Shikoku Office Medical Systems,
Sales Section
Takamatsu NK Bldg. 9F,
1-6-1 Ban-cho,
Takamatsu-shi, Kagawa
760-0017 Japan | Distribution of Medical Diagnostic Imaging
Devices and Systems |
| /26 | c/o Shimadzu Corporation
Matsuyama Sales Office
Pure Dogo 1F,
5-48 Dogoimaichi,
Matsuyama-shi, Ehime
790-0845 Japan | Distribution of Medical Diagnostic Imaging
Devices and Systems |
| /27 | c/o Shimadzu Corporation
Tokushima Sales Office
6-7-2 Sumiyoshi,
Tokushima-shi, Tokushima
770-0861 Japan | Distribution of Medical Diagnostic Imaging
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1, Nishinokyo-Kuwabaracho,
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604-8511 Japan

The scope of certification also covers the following:

- | | | |
|-----|---|---|
| /28 | c/o Shimadzu Corporation
Kochi Sales Office
Seiryō Heights,
1-4-17 Chiyoricho,
Kochi-shi, Kochi
780-0806 Japan | Distribution of Medical Diagnostic Imaging
Devices and Systems |
| /29 | c/o Shimadzu Corporation
Kyushu Office Medical Systems,
Sales Section
Shimadzu Hakata Bldg. 4F,
4-20 Reisen-machi, Hakata-ku,
Fukuoka-shi, Fukuoka
812-0039 Japan | Distribution of Medical Diagnostic Imaging
Devices and Systems |
| /30 | c/o Shimadzu Corporation
Kita-Kyusyu Sales Office
2-8-11 Katanoshinmachi, Kokurakita-ku,
Kitakyusyu-shi, Fukuoka
802-0062 Japan | Distribution of Medical Diagnostic Imaging
Devices and Systems |

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1, Nishinokyo-Kuwabaracho,
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604-8511 Japan

The scope of certification also covers the following:

- | | | |
|-----|--|---|
| /31 | c/o Shimadzu Corporation
Tosu Sales Office
1311-8 Motomachi,
Tosu-shi, Saga
841-0051 Japan | Distribution of Medical Diagnostic Imaging
Devices and Systems |
| /32 | c/o Shimadzu Corporation
Oita Sales Office
S-FORT Takasagocho, 2F,
1-30 Takasagocho,
Oita-shi, Oita
870-0029 Japan | Distribution of Medical Diagnostic Imaging
Devices and Systems |
| /33 | c/o Shimadzu Corporation
Nagasaki Sales Office
Sensyu Daini Bldg.
6-32, Chitosemachi,
Nagasaki-shi, Nagasaki
852-8135 Japan | Distribution of Medical Diagnostic Imaging
Devices and Systems |

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1, Nishinokyo-Kuwabaracho,
Nakagyo-ku Kyoto
604-8511 Japan

The scope of certification also covers the following:

- | | | |
|-----|---|---|
| /34 | c/o Shimadzu Corporation
Miyazaki Sales Office
9F Miyazaki President Building,
3-1-47, Tachibanadorihigashi,
Miyazaki-shi, Miyazaki
880-0805 Japan | Distribution of Medical Diagnostic Imaging
Devices and Systems |
| /35 | c/o Shimadzu Corporation
Kagoshima Sales Office
1-33-1 Higashitaniyama,
Kagoshima-shi, Kagoshima
891-0113 Japan | Distribution of Medical Diagnostic Imaging
Devices and Systems |
| /36 | c/o Shimadzu Corporation
Kumamoto Sales Office
2-17-30 Hirata,
Kumamoto-shi, Kumamoto
860-0826 Japan | Distribution of Medical Diagnostic Imaging
Devices and Systems |
| /37 | c/o Shimadzu Corporation
Okinawa Sales Office
Momo Building, #201,
1-11-12 Matsushima,
Naha-shi, Okinawa
902-0069 Japan | Distribution of Medical Diagnostic Imaging
Devices and Systems |

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Maihara

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1, Nishinokyo-Kuwabaracho,
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604-8511 Japan

The scope of certification also covers the following:

- | | | |
|-----|---|---|
| /38 | c/o Shimadzu Corporation
International Operations Department
1-3 Kanda-Nishiki-cho,
Chiyoda-ku, Tokyo
101-8448 Japan | Distribution of Medical Diagnostic Imaging
Devices and Systems |
| /39 | c/o Shimadzu Corporation
Medical Regulation Policy Department
1, Nishinokyo-Kuwabaracho,
Nakagyo-ku, Kyoto
604-8511 Japan | Administration 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

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