

Certificate

Quality Management System

EN ISO 13485:2016

EN ISO 13485:2016/AC:2018

EN ISO 13485:2016/A11:2021

Registration No.: SX 2365675-1

Certificate Holder: Shimadzu Corporation,
Medical Systems Division
1, Nishinokyo Kuwabara-cho,
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.: 150309354-301

Effective date: 2025-05-13

Expiry date: 2028-05-12

Issue date: 2025-05-12

Replaces certificate SX 2365675-1 issued 2023-05-08

This certificate can be validated on <https://www.certipedia.com>



Atsushi Kato

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

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604-8511, Japan

The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o Shimadzu Corporation, Medical Systems Division 1, Nishinokyo Kuwabara-cho, 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:</p> <p>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:</p> <p>Nuclear Magnetic Resonance Imaging Systems, X-Ray Computer Tomography Devices and Diagnostic Ultrasound Systems</p>
/02	c/o Shimadzu Corporation, Sanjo Works 1, Nishinokyo Kuwabara-cho, 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:</p> <p>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:</p> <p>Nuclear Magnetic Resonance Imaging Systems, X-Ray Computer Tomography Devices and Diagnostic Ultrasound Systems</p>

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604-8511, Japan

The scope of certification also covers the following sites:

/03	c/o Shimadzu Corporation Sales & Marketing Dep. 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 Sales & Marketing Dep. Advanced Healthcare Collaboration Group Diagnostics Promotion 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 Interventional X-ray Promotion Group 1-3 Kanda-Nishiki-cho, Chiyoda-ku, Tokyo 101-8448 Japan	Distribution of Medical Diagnostic Imaging Devices and Systems
/06	c/o Shimadzu Corporation Sales & Marketing Dep. 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
/07	c/o Shimadzu Corporation Sales & Marketing Dep. 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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604-8511, Japan

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/08	c/o Shimadzu Corporation Sales & Marketing Dep. 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
/09	c/o Shimadzu Corporation Sales & Marketing Dep. Kitakanto Office Medical Systems, Sales Section Meiji Yasuda Seimei Oomiya Kishikichou Bldg. 8F 1-41 Oomiya Kishikichou Oomiya-ku, Saitama-shi, Saitama 330-0843 Japan	Distribution of Medical Diagnostic Imaging Devices and Systems
/10	c/o Shimadzu Corporation Sales & Marketing Dep. 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
/11	c/o Shimadzu Corporation Sales & Marketing Dep. 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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The scope of certification also covers the following sites:

/12	c/o Shimadzu Corporation Sales & Marketing Dep. 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
/13	c/o Shimadzu Corporation Sales & Marketing Dep. 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
/14	c/o Shimadzu Corporation Sales & Marketing Dep. 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
/15	c/o Shimadzu Corporation Sales & Marketing Dep. 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

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The scope of certification also covers the following sites:

/16	c/o Shimadzu Corporation Sales & Marketing Dep. Kansai Office Medical Systems, Sales Section 24th Floor, Osaka Umeda Twin Towers South, 1-13-1 Umeda, Kita-ku, Osaka-shi, Osaka 530-0001 Japan	Distribution of Medical Diagnostic Imaging Devices and Systems
/17	c/o Shimadzu Corporation Sales & Marketing Dep. 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
/18	c/o Shimadzu Corporation Sales & Marketing Dep. 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
/19	c/o Shimadzu Corporation Sales & Marketing Dep. Okayama Sales Office Sumitomo Seimei Okayama New City Building, 6F, 3-10 Togiyacho, Kita-ku, Okayama-shi, Okayama 700-0826 Japan	Distribution of Medical Diagnostic Imaging Devices and Systems
/20	c/o Shimadzu Corporation Sales & Marketing Dep. 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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The scope of certification also covers the following sites:

/21	c/o Shimadzu Corporation Sales & Marketing Dep. 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
/22	c/o Shimadzu Corporation Sales & Marketing Dep. Yamaguchi Sales Office 5-18 Ogoriminamimachi, Yamaguchi-shi, Yamaguchi 754-0013 Japan	Distribution of Medical Diagnostic Imaging Devices and Systems
/23	c/o Shimadzu Corporation Sales & Marketing Dep. Shimane Sales Office 2698 Naoe, Hikawacho, Izumo-shi, Shimane 699-0631 Japan	Distribution of Medical Diagnostic Imaging Devices and Systems
/24	c/o Shimadzu Corporation Sales & Marketing Dep. 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
/25	c/o Shimadzu Corporation Sales & Marketing Dep. 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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/26	c/o Shimadzu Corporation Sales & Marketing Dep. Tosu Sales Office 1311-8 Motomachi, Tosu-shi, Saga 841-0051 Japan	Distribution of Medical Diagnostic Imaging Devices and Systems
/27	c/o Shimadzu Corporation Sales & Marketing Dep. Oita Sales Office S-FORT Takasagocho, 2F, 1-30 Takasagocho, Oita-shi, Oita 870-0029 Japan	Distribution of Medical Diagnostic Imaging Devices and Systems
/28	c/o Shimadzu Corporation Sales & Marketing Dep. Nagasaki Sales Office Sensyu Daini Bldg. 6-32, Chitosemachi, Nagasaki-shi, Nagasaki 852-8135 Japan	Distribution of Medical Diagnostic Imaging Devices and Systems
/29	c/o Shimadzu Corporation Sales & Marketing Dep. Miyazaki Sales Office 9F Miyazaki President Building, 3-1-41, Tachibanadorihigashi, Miyazaki-shi, Miyazaki 880-0805 Japan	Distribution of Medical Diagnostic Imaging Devices and Systems
/30	c/o Shimadzu Corporation Sales & Marketing Dep. Kagoshima Sales Office 1-33-1 Higashitaniyama, Kagoshima-shi, Kagoshima 891-0113 Japan	Distribution of Medical Diagnostic Imaging Devices and Systems

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/31	c/o Shimadzu Corporation Sales & Marketing Dep. Kumamoto Sales Office 2-17-30 Hirata, Kumamoto-shi, Kumamoto 860-0826 Japan	Distribution of Medical Diagnostic Imaging Devices and Systems
/32	c/o Shimadzu Corporation Sales & Marketing Dep. Okinawa Sales Office Momo Building, #201, 1-11-12 Matsushima, Naha-shi, Okinawa 902-0069 Japan	Distribution of Medical Diagnostic Imaging Devices and Systems
/33	c/o Shimadzu Corporation Sales & Marketing Dep. International Operations Department 1-3 Kanda-Nishiki-cho, Chiyoda-ku, Tokyo 101-8448 Japan	Distribution of Medical Diagnostic Imaging Devices and Systems
/34	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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