

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

© TÜV, TÜV and TÜV are registered trademarks. Utilisation and application requires prior approval.

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

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	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
/02	c/o Shimadzu Corporation, Sanjo Works 1, Nishinokyo Kuwabara-cho, 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

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

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

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 |

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

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

The scope of certification also covers the following sites:

- | | | |
|-----|--|--|
| /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 |

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

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

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 |

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

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

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 Togyacho,
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 |

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

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

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 |

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

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

The scope of certification also covers the following sites:

- | | | |
|-----|---|--|
| /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 |

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

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

The scope of certification also covers the following sites:

- | | | |
|-----|--|---|
| /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 |

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