

# Certificate

Standard: **ISO 13485:2016, JIS Q 13485:2018**

Certificate Registr. No.: **81 105 096363**

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

including the locations according to annex

Scope: Design, Development, Manufacturing, Importing and Sales 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

Proof has been furnished by means of an audit that the requirements of ISO 13485:2016, JIS Q 13485:2018 are met.

Validity: The certificate is valid from 2019-05-13 until 2022-05-12.  
First certification 2010

2019-04-23



TÜV Rheinland Japan Ltd.  
3-19-5 Shin-Yokohama, Kohoku-ku,  
Yokohama 222-0033, Japan

# Annex to certificate

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<b>No.</b>	<b>Location</b>	<b>Scope</b>
/01	Shimadzu Corporation, Medical Systems Division 1, Nishinokyo-Kuwabaracho, Nakagyo-ku, Kyoto 604-8511, Japan	Design, Development, Manufacturing, Importing and Sales 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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<b>No.</b>	<b>Location</b>	<b>Scope</b>
/39	Shimadzu Corporation, Sanjo Works (Shimadzu Corporation, Sanjo Factory) 1, Nishinokyo-Kuwabaracho, Nakagyo-ku, Kyoto 604-8511, Japan	Design, Development, Manufacturing, Importing and Sales 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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<b>No.</b>	<b>Location</b>	<b>Scope</b>
/36	Sales Planning Section: 1-3 Kanda-Nishiki-cho, Chiyoda-ku, Tokyo 101-8448, Japan	Sales of Medical Diagnostic Imaging Devices and Systems
/37	Promotion section for Cardiac Vascular System: 1-3 Kanda-Nishiki-cho, Chiyoda-ku, Tokyo 101-8448, Japan	Same as above
/40	National Sales Channel Management Section: 1-3 Kanda-Nishiki-cho, Chiyoda-ku, Tokyo 101-8448, Japan	Same as above
/28	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	Same as above
/29	Tohoku Office Medical Systems, Sales Section: Prime Square Hirose-dori Bldg. 12F, Chuo 2-9-27, Aoba-ku, Sendai-shi, Miyagi 980-0021, Japan	Same as above

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<b>No.</b>	<b>Location</b>	<b>Scope</b>
/30	Akita Sales Office: Toda Bldg. 2-25, Higashidori Nakamachi, Akita-shi, Akita 010-0002, Japan	Sales of Medical Diagnostic Imaging Devices and Systems
/05	Koriyama Sales Office: Koriyama Fukoku Seimei Bldg. 2F, 6-7 Domaecho, Koriyama-shi, Fukushima 963-8877, Japan	Same as above
/02	Tokyo Office Medical Systems, Sales Section: 1-3 Kanda-Nishiki-cho, Chiyoda-ku, Tokyo 101-8448, Japan	Same as above
/03	Chiba Sales Office: Daiso Center Bldg. 3F, 2-7-2 Shinchiba, Chuo-ku, Chiba-shi, Chiba 260-0031, Japan	Same as above
/04	Yamanashi Sales Office: Green Heights Tachibana 101, 2-4-10 Sumiyoshi, Kofu-shi, Yamanashi 400-0851, Japan	Same as above

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No.	Location	Scope
/27	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	Sales of Medical Diagnostic Imaging Devices and Systems
/06	Nagoya Office Medical Systems, Sales Section: Nagoya Kokusai Center Bldg. 19F, 1-47-1 Nagono, Nakamura-ku, Nagoya-shi, Aichi 450-0001, Japan	Same as above
/07	Kyoto Office Medical Systems, Sales Section: 1 Nishinokyo-Tokudaijicho, Nakagyo-ku, Kyoto-shi, Kyoto 604-8445, Japan	Same as above
/08	Shiga Sales Office: Daini-Kojima Bldg. 1F, 300-21 Fuke-Cho, Moriyama-shi, Shiga 524-0033, Japan	Same as above

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No.	Location	Scope
/09	Kansai Office Medical Systems, Sales Section: Hankyu Terminal Bldg. 14F, 1-1-4 Shibata, Kita-ku, Osaka-shi, Osaka 530-0012, Japan	Sales of Medical Diagnostic Imaging Devices and Systems
/14	Kobe Sales Office: Eikoh Bldg. 9F, 93 Edo-machi, Chuo-ku, Kobe-shi, Hyogo 650-0033, Japan	Same as above
/11	Nara Sales Office: Nissei Naraekimae Bldg. 4F, 1-1-15 Omiyacho, Nara-shi, Nara 630-8115, Japan	Same as above
/12	Okayama Sales Office: Sumitomo Seimei Okayama Newcity Bldg. 6F, 3-10 Togiyacho, Kita-ku, Okayama-shi, Okayama 700-0826, Japan	Same as above
/13	Tottori Sales Office: 6-1-32 Shinkai, Yonago-shi, Tottori 683-0801, Japan	Same as above

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<b>No.</b>	<b>Location</b>	<b>Scope</b>
/15	Hiroshima Office Medical Systems, Sales Section: Meiji Yasuda Seimei Hiroshima Bldg. 15F, 4-25, Fukuro-machi, Naka-ku, Hiroshima-shi, Hiroshima 730-0036, Japan	Sales of Medical Diagnostic Imaging Devices and Systems
/16	Yamaguchi Sales Office: 5-18 Ogoriminamimachi, Yamaguchi-shi, Yamaguchi 754-0013, Japan	Same as above
/17	Shimane Sales Office: 2698 Naoe, Hikawacho, Izumo-shi, Shimane 699-0631, Japan	Same as above
/31	Shikoku Office Medical Systems, Sales Section: Takamatsu NK Bldg. 9F, 1-6-1 Ban-cho, Takamatsu-shi, Kagawa 760-0017, Japan	Same as above
/32	Matsuyama Sales Office: Pure Dogo 1F, 5-48 Dogoimaichi, Matsuyama-shi, Ehime 790-0845, Japan	Same as above



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No.	Location	Scope
/33	Tokushima Sales Office: 6-7-2 Sumiyoshi, Tokushima-shi, Tokushima 770-0861, Japan	Sales of Medical Diagnostic Imaging Devices and Systems
/34	Kochi Sales Office: Seiry Heights, 1-4-17 Chiyoricho, Kochi-shi, Kochi 780-0806, Japan	Same as above
/19	Kyushu Office Medical Systems, Sales Section: Shimadzu Hakata Bldg. 4F, 4-20 Reisen-machi, Hakata-ku, Fukuoka-shi, Fukuoka 812-0039, Japan	Same as above
/20	Kita-Kyusyu Sales Office: 2-8-11 Katanoshinmachi, Kokurakita-ku, Kitakyusyu-shi, Fukuoka 802-0062, Japan	Same as above
/21	Tosu Sales Office: 1311-8 Motomachi, Tosu-shi, Saga 841-0051, Japan	Same as above
/22	Oita Sales Office: 176-1 Houjyo, Oita-shi, Oita 870-0855, Japan	Same as above

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No.	Location	Scope
/25	Nagasaki Sales Office: Sensyu Daini Bldg. 6-32, Chitosemachi, Nagasaki-shi, Nagasaki 852-8135, Japan	Sales of Medical Diagnostic Imaging Devices and Systems
/23	Miyazaki Sales Office: 952-1 Tsunehisa, Miyazaki-shi, Miyazaki 880-0916, Japan	Same as above
/24	Kagoshima Sales Office: 1-33-1 Higashitaniyama, Kagoshima-shi, Kagoshima 891-0113, Japan	Same as above
/26	Kumamoto Sales Office: 2-20-45 Hirata, Kumamoto-shi, Kumamoto 860-0826, Japan	Same as above


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No.	Location	Scope
/38	International Operations Department: 1-3 Kanda-Nishiki-cho, Chiyoda-ku, Tokyo 101-8448, Japan	Sales of Medical Diagnostic Imaging Devices and Systems

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Yokohama 222-0033, Japan

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