



By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that: Canon Medical Systems Corporation
1385, Shimoishigami
Otawara-shi
Tochigi
324-8550
Japan

キャノンメディカルシステムズ株式会社
〒324-8550
栃木県
大田原市
下石上1385番地

Holds Certificate No: MD 759595

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2021-11-03

Latest Revision Date: 2022-05-16

Effective Date: 2022-09-10

Expiry Date: 2025-09-09

Page: 1 of 4



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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

Certificate No: MD 759595

Registered Scope:

Design and development, manufacture, installation, maintenance and distribution of Mobile & stationary Diagnostic X-Ray Systems, Mobile & stationary Fluoroscopic X-Ray Systems, X-ray Computed Tomography Systems, Diagnostic Ultrasound Systems, Magnetic Resonance Imaging Systems, Nuclear medicine imaging systems, In vitro diagnostic clinical test equipment, Picture archiving & communication systems (PACS), Workstation and Workstation Software.

Installation, maintenance and distribution of therapeutic equipment

Design and development, manufacture and distribution of in vitro diagnostic test kit (immunology, gene technology, clinical chemistry)

移動用・設置用 X 線診断システム、移動用・設置用 X 線透視システム、X 線 CT 診断システム、超音波診断システム、MRI システム、核医学診断システム、体外診断用検体検査装置、医用画像ファイリングシステム (PACS)、ワークステーション及びワークステーションソフトウェアの設計・開発、製造、据付、保守、及びディストリビューション

治療装置の据付、保守、及びディストリビューション

体外診断用医薬品（免疫学的検査、遺伝学的検査、生化学検査）の設計・開発、製造及びディストリビューション

Original Registration Date: 2021-11-03

Latest Revision Date: 2022-05-16

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Certificate No: MD 759595

Location	Registered Activities
Canon Medical Systems Corporation 1385, Shimoishigami Otawara-shi Tochigi 324-8550 Japan キヤノンメディカルシステムズ株式会社 本社 〒324-8550 栃木県 大田原市 下石上1385番地	Design and development, manufacture, installation, maintenance and distribution of Mobile & stationary Diagnostic X-Ray Systems, Mobile & stationary Fluoroscopic X-Ray Systems, X-ray Computed Tomography Systems, Diagnostic Ultrasound Systems, Magnetic Resonance Imaging Systems, Nuclear medicine imaging systems, In vitro diagnostic clinical test equipment, Picture archiving & communication systems (PACS), Workstation and Workstation Software. Installation, maintenance and distribution of therapeutic equipment Design and development, manufacture and distribution of in vitro diagnostic test kit (immunology, gene technology, clinical chemistry) 移動用・設置用X線診断システム、移動用・設置用X線透視システム、X線CT診断システム、超音波診断システム、MRIシステム、核医学診断システム、体外診断用検体検査装置、医用画像ファイリングシステム（PACS）、ワークステーション及びワークステーションソフトウェアの設計・開発、製造、据付、保守、及びディストリビューション 治療装置の据付、保守、及びディストリビューション 体外診断用医薬品（免疫学的検査、遺伝学的検査、生化学検査）の設計・開発、製造及びディストリビューション
Canon Medical Systems Corporation Kawasaki Office 70-1, Yanagi-cho, Saiwai-ku, Kawasaki-Shi, Kanagawa 212-0015 Japan キヤノンメディカルシステムズ株式会社 川崎事業所 〒212-0015 神奈川県 川崎市 幸区柳町70-1	Distribution of diagnostic imaging systems, therapeutic equipment, in vitro diagnostic clinical test equipment, picture archiving & communication systems (PACS), workstation, workstation software and in vitro diagnostic test kit (immunology, gene technology, clinical chemistry) 画像診断システム、治療装置、体外診断用検体検査装置、医用画像ファイリングシステム（PACS）、ワークステーション、ワークステーションソフトウェア及び体外診断用医薬品（免疫学的検査、遺伝学的検査、生化学検査）のディストリビューション

Original Registration Date: 2021-11-03

Latest Revision Date: 2022-05-16

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BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
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Certificate No: MD 759595

Location	Registered Activities
Okinawa Canon Medical Systems Co., Ltd. 1-19-9 Nishi, Naha-shi, Okinawa 900-0036 Japan 沖縄キャノンメディカルシステムズ株式会社 〒900-0036 沖縄県 那覇市 西1丁目19番地9号	Installation, maintenance and distribution of diagnostic imaging systems, therapeutic equipment, in vitro diagnostic clinical test equipment, picture archiving & communication systems (PACS), workstation and workstation software 画像診断システム、治療装置、体外診断用検体検査装置、医用画像ファイリングシステム（PACS）、ワークステーション及びワークステーションソフトウェアの据付、保守、及びディストリビューション

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BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that: Canon Medical Systems Corporation
1385, Shimoishigami
Otawara-shi
Tochigi
324-8550
Japan

キヤノンメディカルシステムズ株式会社
〒324-8550
栃木県
大田原市
下石上1385番地

Holds Certificate No: FM 759586

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

Please see scope page.

For and on behalf of BSI:

Michael Lam - Managing Director Assurance, APAC

Original Registration Date: 1992-12-22

Latest Revision Date: 2022-05-27

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Expiry Date: 2025-09-30

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BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

Certificate No: FM 759586

Registered Scope:

Design, development, manufacture, installation, maintenance and distribution of diagnostic imaging systems, in vitro diagnostic clinical test equipment, picture archiving & communication systems (PACS), medical service supporting IT systems, workstation and workstation software
Installation, maintenance and distribution of therapeutic equipment
Design, development, manufacture and distribution of molecular test devices and power supply component
Design, development, manufacture and distribution of in vitro diagnostic test kit (immunology, gene technology and clinical chemistry) and molecular test reagents
Design, development and manufacture of component for MRI
画像診断システム、体外診断用検体検査装置、医用画像ファイリングシステム (PACS)、医療業務支援 IT システム、ワークステーション、及びワークステーションソフトウェアの設計・開発、製造、据付、保守、及びディストリビューション
治療装置の据付、保守、及びディストリビューション
分子検査装置及び電源コンポーネントの設計・開発、製造、及びディストリビューション
体外診断用医薬品（免疫学的検査、遺伝学的検査、生化学検査）及び分子検査試薬の設計・開発、製造、及びディストリビューション
MRI 用コンポーネントの設計・開発及び製造

Original Registration Date: 1992-12-22

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BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

Certificate No: FM 759586

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Canon Medical Systems Corporation 1385, Shimoishigami Otawara-shi Tochigi 324-8550 Japan キヤノンメディカルシステムズ株式会社 本社 〒324-8550 栃木県 大田原市 下石上1385番地	Design, development, manufacture, installation, maintenance, and distribution of imaging systems, in vitro diagnostic clinical test equipment, picture archiving & communication systems (PACS), medical service supporting IT systems, workstation and workstation software Installation, maintenance, and distribution of therapeutic equipment Design, development, manufacture, and distribution of molecular test devices and power supply component Design, development, manufacture and distribution of in vitro diagnostic test kit (immunology, gene technology and clinical chemistry) and molecular test reagents 画像診断システム、体外診断用検体検査装置、医用画像ファイリングシステム (PACS)、医療業務支援 IT システム、ワークステーション及びワークステーションソフトウェアの設計・開発、製造、据付、保守、及びディストリビューション 治療装置の据付、保守、及びディストリビューション 分子検査装置及び電源コンポーネントの設計・開発、製造、及びディストリビューション 体外診断用医薬品（免疫学的検査、遺伝学的検査、生化学検査）及び分子検査試薬の設計・開発、製造、及びディストリビューション
Canon Medical Systems Corporation Kawasaki Office 70-1, Yanagi-cho, Saiwai-ku, Kawasaki-Shi, Kanagawa 212-0015 Japan キヤノンメディカルシステムズ株式会社 川崎事業所 〒212-0015 神奈川県 川崎市 幸区柳町70-1	Distribution of diagnostic imaging systems, therapeutic equipment, in vitro diagnostic clinical test equipment, workstation and workstation software Design, development, installation, maintenance and distribution of picture archiving & communication systems (PACS) and medical service supporting IT systems 画像診断システム、治療装置、体外診断用検体検査装置、ワークステーション及びワークステーションソフトウェアのディストリビューション 医用画像ファイリングシステム (PACS) 及び医療業務支援 IT システムの設計・開発、据付、保守、及びディストリビューション

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Okinawa Canon Medical Systems Co., Ltd. 1-19-9 Nishi, Naha-shi, Okinawa 900-0036 Japan 沖縄キャノンメディカルシステムズ株式会社 〒900-0036 沖縄県 那覇市 西1丁目19番地9号	Installation, maintenance, and distribution of diagnostic imaging systems, therapeutic equipment, in vitro diagnostic clinical test equipment, picture archiving & communication systems (PACS), workstation and workstation software 画像診断システム、治療装置、体外診断用検体検査装置、医用画像ファイリングシステム（PACS）、ワークステーション及びワークステーションソフトウェアの据付、保守、及びディストリビューション
Canon Medical Systems Corporation Kansai Office 1-1-30 Oyodo-naka, Kita-ku, Osaka-shi, Osaka 531-6106 Japan キャノンメディカルシステムズ株式会社 関西支社 〒531-6106 大阪府 大阪市 北区大淀中1丁目1番30号	Design, development, installation, maintenance, and distribution of medical service supporting IT systems 医療業務支援 IT システムの設計・開発、据付、保守、及びディストリビューション
Canon Medical Systems Corporation Ako Office 651, Tenwa, Ako-shi, Hyogo 678-0256 Japan キャノンメディカルシステムズ株式会社 赤穂事業所 〒678-0256 兵庫県 赤穂市 天和651番地	Design, development and manufacture of component for MRI MRI 用コンポーネントの設計・開発及び製造

Original Registration Date: 1992-12-22

Effective Date: 2022-05-27

Latest Revision Date: 2022-05-27

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