

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Canon Medical Informatics, Inc.
5850 Opus Parkway
Suite 300
Minnetonka
Minnesota
55343
USA

Facility ID Number: F000473

Holds Certificate No:

MDSAP 685656

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

Brazil: RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009

Canada: Medical Devices Regulations - Part 1 - SOR 98/282

Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act

USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Design and development, production, distribution, installation, and servicing of software for medical imaging applications.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2019-03-19

Effective Date: 2022-09-20

Expiry Date: 2024-10-25



BSI Group America Inc. is an MDSAP recognised auditing organization