

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Canon Medical Informatics Incorporated

Main Site: 19 Regina Street North,
Waterloo, Ontario, N2J 2Z9, Canada (FIN F000864)

Additional site1: Canon Medical Informatics A/S
Krumtappen 4, Etage 3, 2500 Valby, Denmark (FIN F001990)

Additional site2: Canon Medical Informatics B.V./ Canon Medical Informatics Europe B.V.
Wiltonstraat 41, 3905, KW Veenendaal, Netherlands (FIN F005088)

has been registered by Intertek, an MDSAP recognized auditing organization, as conforming to the requirements of:

ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6)

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

United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

The management system is applicable to:

Design and development, manufacture, installation and service of software viewing and analyzing of medical images.

Main site: Management, Purchasing, Installation and Servicing

Additional site1: Management, Design, Manufacturing, Purchasing, Installation and Servicing

Additional site2: Management, Installation and Servicing

Certificate Number:

0074642-05

Initial Certification Date:

2018-04-24

Date of Certification Decision:

2023-07-11

Certification Effective Date:

2023-07-11

Certification Expiry Date:

2024-04-23



intertek

Calin Moldovean

President, Business Assurance

Intertek Testing Services NA, Inc.
900 Chelmsford Street
Lowell, MA, USA 01851

