

# CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

## Canon Medical Informatics A/S

Main Site: Krumtappen 4, Etage 3, 2500 Valby, Denmark (FIN F001990)

Additional site1: Canon Medical Informatics Incorporated  
19 Regina Street North, Waterloo, Ontario, N2J 2Z9, Canada (FIN F000864)

Additional site2: 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, Design, Manufacturing, Purchasing, Installation and Servicing*

*Additional site1: Management, Purchasing, Installation and Servicing*

*Additional site2: Management, Installation and Servicing*

**Certificate Number:**

0074642-06

**Initial Certification Date:**

2018-04-24

**Date of Certification Decision:**

2024-04-13

**Certification Effective Date:**

2024-04-23

**Certification Expiry Date:**

2027-04-23



**intertek**

A handwritten signature in black ink, appearing to read "Calin Moldovean", written over a horizontal line.

**Calin Moldovean**

President, Business Assurance

Intertek Testing Services NA, Inc.  
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