

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

Holds Certificate Number:

FM 95460

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

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 Global Regulatory & Quality

Original Registration Date: 2005-07-11

Latest Revision Date: 2024-10-02

Effective Date: 2024-10-26

Expiry Date: 2027-10-25

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