



By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: **Carestream Health, Inc.**
150 Verona Street
Rochester
New York
14608
USA

Holds Certificate No: **FM 701584**

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

The design, manufacture, distribution, (integration, installation and servicing excluding film products) of diagnostic image recording devices, photo chemicals, medical and dental imaging systems, cone beam computed tomography, information technology software for healthcare information systems and medical imaging and detection. Manufacture, service, installation and distribution of Dry View Printers. Storage, Handling, Packaging and Distribution of Pharmaceutical Products.

Gary E Slack

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2008-12-20

Latest Revision Date: 2021-02-19

Effective Date: 2019-10-03

Expiry Date: 2022-10-02

Page: 1 of 2



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This certificate remains the property of BSI and shall be returned immediately upon request. An electronic certificate can be authenticated [online](#). Printed copies can be validated at [www.bsigroup.com/ClientDirectory](#). To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.

Nguyễn Hoàng Thùy Vi
TỔNG QUẢN LÝ



Certificate No: **FM 701584**

Location	Registered Activities
Carestream Health, Inc. 150 Verona Street Rochester New York 14608 USA	Complaint Handling, Incident & Recall Reporting, Device Registration & Regulatory Requirements, Administration.
Carestream Health Inc. 882 Linden Ave. Rochester New York 14625 USA	Storage, Handling, Packaging and Distribution of Finished Devices, and Replacement Parts. The Storage, Handling, Packaging and Distribution of Pharmaceutical Products.
Carestream Health, Inc 1049 West Ridge Road Rochester New York 14615 USA	The assembly, integration and distribution of image management systems. The design and manufacture of cassettes, and intensifying and storage phosphor screens. The design, manufacture, service, and installation of medical x-ray equipment systems, cone beam computed tomography, medical imaging systems including software and accessories. The manufacturing of X-ray detectors.
Carestream Health, Inc 1669 Lake Avenue Rochester New York 14652 USA	The manufacture of dental and medical x-ray films, intensifying and Storage phosphor screen chemicals. The design and development of dental x-ray film systems and media used in medical imaging.



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