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By Royal Charter

# EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

**No.** CE 01233  
**Issued To:** Carestream Health, Inc.  
150 Verona Street  
Rochester  
New York  
14608  
USA

In respect of:

**The design, development and manufacture of diagnostic image recording devices including storage phosphor screens and reader systems, medical x-ray films, direct digital radiography systems, dental x-ray systems including film, dental and medical imaging equipment, and medical imaging and PACS Software. Those aspects of metrology related to the design and manufacture of dimensional measuring PACS software.**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Albert Roossien, Regulatory Lead

First Issued: **1996-03-06**

Date: **2019-02-27**

Expiry Date: **2021-03-05**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.  
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, 389 Chiswick Park Avenue, Uxbridge, Middlesex, UK  
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.  
A member of BSI Group of Companies.





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## EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

### List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 01233**  
Date: **2019-02-27**  
Issued To: **Carestream Health, Inc.**  
**150 Verona Street**  
**Rochester**  
**New York**  
**14608**  
**USA**

<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Agfa-Gevaert HealthCare GmbH Bürgermeister-Götz-Str. 10 Schrobenhausen 86529 Germany	<b>Manufacture</b>
Algotec Systems Ltd 2 Hapnina Street PO BOX 46 43107 Ra'anana Israel	<b>Design</b> <b>Development</b> <b>Software</b>
Analogic Corporation 8 Centennial Drive Peabody Massachusetts 01960 USA	<b>Design</b> <b>Manufacture</b>

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New York  
14608  
USA**

<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Carestream Health France 1, rue Galilée 93192 NOISY-LE-GRAND CEDEX France	<b>EU Representative</b>
Carestream Health, Inc 5450 Campus Drive Canandaigua New York 14424 USA	<b>Manufacture</b>
Carestream Health, Inc. 1049 West Ridge Road Rochester New York 14615 USA	<b>Design Development Manufacture</b>

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**14608**  
**USA**

<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Carestream Health, Inc. 1669 Lake Avenue Rochester New York 14652 USA	<b>Design</b> <b>Development</b> <b>Manufacture</b>
Carestream Health, Inc. 1964 Lake Ave Rochester New York 14615 USA	<b>Design</b>
Carestream Health, Inc. 2000 Howard Smith Avenue West Windsor Colorado 80550 USA	<b>Manufacture</b>

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Rochester  
New York  
14608  
USA**

<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Carestream Health, Inc. 8124 Pacific Avenue White City Oregon 97503 USA	<b>Manufacture</b>
Carestream Health, Inc. Global R & D Center (Shanghai) No. 27 Xinqing Road Shanghai 201206 China	<b>Design Development</b>
Communication & Power Industries Canada Inc. 45 River Drive Georgetown Ontario L7G 2J4 Canada	<b>Manufacture</b>

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**New York**  
**14608**  
**USA**

<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Micro-X Ltd 1284 South Road Clovelly Park South Australia 5042 Australia	<b>Design</b> <b>Manufacture</b>
Rayco (Shanghai) Medical Products Company Limited Building 7, No. 1510 Chuanqiao Road China (Shanghai) Pilot Free Trade Z Shanghai 201206 China	<b>Manufacture</b>

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**New York**  
**14608**  
**USA**

<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Rayco (Xiamen) Medical Products Company Limited 308 Wengjiao Road Haicang District Xiamen Fujian 361022 China	<b>Manufacture</b>
ScImage, Inc. 4916 El Camino Real, Suite 200 Los Altos California 94022 USA	<b>Design Development Software</b>

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**150 Verona Street**  
**Rochester**  
**New York**  
**14608**  
**USA**

**Subcontractor:**

**Service(s) supplied**

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Soluciones Médicas Exportación  
S de RL de CV  
Calle Anillo Periferico Poniente No. 3100  
Colonia Paraísos Del Colli  
Zapopan  
Jalisco  
45069  
Mexico

**Manufacture**

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Varian Medical Systems, Inc.  
X-Ray Products  
1678 South Pioneer Road  
Salt Lake City  
Utah  
84104  
USA

**Manufacture**

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# 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.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2008-12-20

Latest Revision Date: 2019-09-24

Effective Date: 2019-10-03

Expiry Date: 2022-10-02

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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 U.S.A.  
A Member of the BSI Group of Companies.



Certificate No: **FM 701584**

Location	Registered Activities
Carestream Health, Inc 150 Verona Street Rochester New York 14608 USA	The design, manufacture, distribution, (integration, installation and servicing excluding film products) of diagnostic image recording devices, photo chemicals, medical 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.
Carestream Health Inc. 1600 Lexington Ave. Suite #356 Rochester New York 14606 USA	Storage, Handling, Packaging and Distribution of Finished Devices, and Replacement Parts, the Storage, Handling, Packaging and Distribution of Pharmaceutical Products.
Carestream Health, Inc. Smart System Technology and Commercialization Center (STC) 5450 Campus Drive Canandaigua New York 14424 USA	The manufacture of X-ray detectors.
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.
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.
Carestream Health, Inc 1964 Lake Avenue Rochester New York 14652 USA	The design and development of dental x-ray film systems and media used in medical imaging.

Original Registration Date: 2008-12-20

Latest Revision Date: 2019-09-24

Effective Date: 2019-10-03

Expiry Date: 2022-10-02

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# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

Carestream Health, Inc  
150 Verona Street  
Rochester  
New York  
14608  
USA


Holds Certificate No:

**FM 537916**

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

The design, development, manufacture, and service of digital radiography imaging systems (such as INDUSTREX digital systems) and accessories for the non-destructive testing industry.

For and on behalf of BSI:

  
Carlos Pitanga, Chief Operating Officer Assurance – Americas

Original Registration Date: 2008-07-17

Effective Date: 2019-10-21

Latest Revision Date: 2019-09-24

Expiry Date: 2022-10-20

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To be read in conjunction with the scope above or the attached appendix.  
Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: 01908 545700.  
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W6 7AL, UK.  
A Member of the BSI Group of Companies.

Certificate No: **FM 537916**

Location

Registered Activities

Carestream Health, Inc  
150 Verona Street  
Rochester  
New York  
14608  
USA

The design, development, manufacture, and service of digital radiography imaging systems (such as INDUSTREX digital systems) and accessories for the non-destructive testing industry.

Carestream Health, Inc  
1049 West Ridge Road  
Rochester  
New York  
14615  
USA

The design and manufacture of digital radiography imaging systems (such as INDUSTREX digital systems) and accessories for the non-destructive testing industry.

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