

bsi.



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.

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

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](http://www.bsigroup.com/Clients). Printed copies can be validated at www.bsigroup.com/Clients.
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.

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

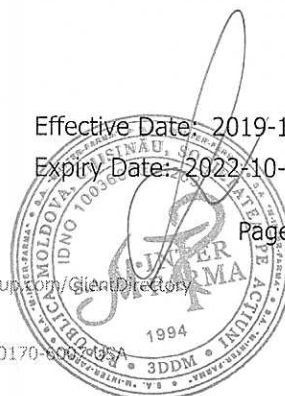
Expiry Date: 2022-10-02

Page: 2 of 2

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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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Page 1 of 1

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, Say Building, John M. Keynesplein 9, 1056 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
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

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

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Date: **2019-02-27**
Issued To: **Carestream Health, Inc.**
150 Verona Street
Rochester
New York
14608
USA

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

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150 Verona Street
Rochester
New York
14608
USA**

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

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150 Verona Street
Rochester
New York
14608
USA

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

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Date: **2019-02-27**
Issued To: **Carestream Health, Inc.**
150 Verona Street
Rochester
New York
14608
USA

Subcontractor:

Service(s) supplied

Micro-X Ltd
1284 South Road
Clovelly Park
South Australia
5042
Australia

Design
Manufacture

Rayco (Shanghai) Medical Products
Company Limited
Building 7, No. 1510 Chuanqiao Road
China (Shanghai) Pilot Free Trade Z
Shanghai
201206
China

Manufacture

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150 Verona Street
Rochester
New York
14608
USA

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

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

List of Significant Subcontractors

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

Subcontractor:

Service(s) supplied

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

Manufacture

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

Manufacture

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DECLARATION OF CONFORMITY

Carestream Health, Inc., hereby declares that the product(s) listed are made in conformity with:
Medical Device Directive [Directive 93/42/EEC], ANNEX VII Conformity Assessment Procedure and the Australian
Therapeutic Goods (Medical Devices) Regulations 2002, Clause 6.6 of Schedule 3.

Manufacturer's Name and Address: Carestream Health, Inc.
150 Verona Street
Rochester, New York, USA 14608

Medical Device: Non-X-ray Film, Sheet

Product List: DRYVIEW DVB Laser Imaging Film
DRYVIEW DVB+ Laser Imaging Film
DRYVIEW DVB+ Premium Laser Imaging Film
DRYVIEW DVC Laser Imaging Film
DRYVIEW DVE Laser Imaging Film
DRYVIEW DVM Mammography Laser Imaging Film
DRYVIEW DVM+ Mammography Laser Imaging Film
—End of List—

Device Classification: Europe - Class I, ANNEX IX, Rule I
Australia - Class I, Schedule 2, Part 2, Rule 2. 1

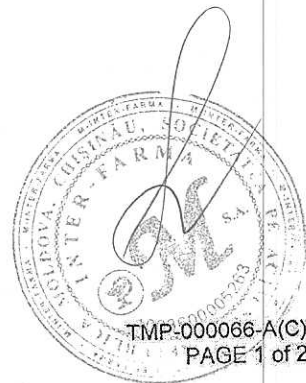
GMDN Code and Term: 40980. Medical x-ray film, non-screen

Scope of Application: All declared products

Each kind of medical device to which the Declaration of Conformity (not requiring assessment by the Secretary) procedures have been applied complies with the applicable provisions of the essential principles and the classification rules before being supplied.

Quality-Management-System Certified to EN ISO 13485 by:
BSI No. FM 701584
BSI No. FM 46141
TUV No. Q2N 17 11 61500 005
BSI No. FM 507315

Issue date: 11 February 2019, Revision K (DRYVIEW Imaging Film)
Carestream Health, Inc. | 150 Verona Street | Rochester, New York 14608 | USA

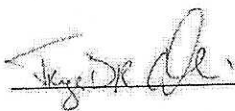


TMP:000066-A(C)
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European Authorized Representative: Carestream Health France
1, rue Galilée
93192 NOISY-LE-GRAND CEDEX
FRANCE

The relevant sections of the following European Union Harmonized standards apply to the listed product(s):

EN ISO 14971
EN 1041
EN ISO 15223-1
EN 62366



Treya D. R. Collins
Director, Global Quality Systems
Carestream Health, Inc.
150 Verona Street
Rochester, New York 14608, USA
Telephone: +1-970-304-4654

