

Carestream

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 II Conformity Assessment Procedure and the Australian
Therapeutic Goods (Medical Devices) Regulations 2002, Clause 1.8 of Schedule 3.

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

Medical Device: X-ray Film, Sheet

Product List:
X-OMAT BT Film
Medical X-ray Blue / MXB Film
Medical X-ray Blue / MXBE Film
Medical X-ray Green / MXG Film
T-MAT G/RA Film
T-MAT L/RA Film
INSIGHT Pediatric Film
INSIGHT Thoracic Film
X-SIGHT G/RA Film
MIN-R EV Film
MIN-R S Film
MIN-R 2000 Plus Film
L Green X-ray Film WB
HG Green X-ray Film WB
Green X-ray Film WB
Full Blue X-ray Film WB
Mammo Film WB
—End of List—

Device Classification: Europe - Class IIa, ANNEX IX, Rule 16
Australia - Class IIa, Schedule 2, Part 5, Rule 5.4

GMDN Code and Term: 40979, Medical x-ray film, screen

Scope of Application: All declared products

Each kind of medical device to which the quality-management system has been applied complies with the applicable provisions of the essential principles, the classification rules, and the full-quality-assurance procedures at each stage, from the design of the device until its final inspection before being supplied.

Issue date: 20 March 2019, Revision X (X-ray Film, Sheet - Class IIa)
Carestream Health, Inc. | 150 Verona Street | Rochester, New York 14608 USA

TMP-000066-A(C)
PAGE 1 of 2



Quality-Management-System

Certified to EN ISO 13485 by
BSI No. FM 701584
BSI No. FM 507315
DNV No. 245266-2017-AQ-USA-NA-PS Rev. 1
BSI No. FM 46141
TUV No. Q2N 17 1 61500 005

European Notified Body:

British Standards Institute, BSI (2797)

Full-Quality-Assurance-System
Certificate (CE):

BSI Certificate Number CE 01233

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



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

Issue date: 20 March 2019, Revision X (X-ray Film, Sheet- Class Ila)
Carestream Health, Inc. | 150 Verona Street | Rochester, New York 14608 | USA



ME-000066-A(C)
PAGE 2 of 2

Carestream

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 VI 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: Medical Imaging Photoprocessing Devices - Photochemicals

Product List: Chemistry used to develop or fix the image on medical and dental X-ray films:
GBX Developer and Replenisher
GBX Fixer and Replenisher
GBX Twin Pack
X-OMAT MX Fixer and Replenisher
X-OMAT MX Developer and Replenisher
READYMATIC Developer and Replenisher
READYMATIC Fixer and Replenisher
READYMATIC Chem Pack
RP X-OMAT Developer and Replenisher
RP X-OMAT LO Fixer and Replenisher
X-OMAT EX II Developer and Replenisher
X-OMAT Developer Starter
X-OMAT LE+ Developer and Replenisher
X-OMAT LE+ Fixer and Replenisher
CARESTREAM DENTAL X-ray Monobath
CARESTREAM DENTAL X-ray Developer
CARESTREAM DENTAL X-ray Fixer
Rapid Access Twin Pack
Rapid Access Developer
Rapid Access Fixer
XCE Developer and Replenisher
XCF Fixer and Replenisher
XPE Developer
XPF Fixer
—End of List—

Device Classification: Europe - Class I, ANNEX IX, Rule 1
Australia - Class I, Schedule 2, Part 2, Rule 2.1

GMDN Code and Term: 41009 Radiographic film processing chemical, automated
41008 Radiographic film processing chemical, manual

Issue date: 8 April 2018, Revision T Photochemistry
Carestream Health, Inc. | 150 Verona Street | Rochester, New York 14608 | USA



P-000066-A(C)
PAGE 1 of 2

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

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 1041
EN ISO 15223-1
EN ISO 14971
EN 62366



Kevin C. Wright
Senior Director, Worldwide Regulatory Affairs
Carestream Health, Inc.
150 Verona Street
Rochester, New York 14608, USA
Telephone: +1-585-627-6878



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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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Page 1 of 1

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

Information and Contact: BSI, Sky Building, 389 Chiswick Park Avenue, Uxbridge, Middlesex, UK. The Netherlands: BSI Group The Netherlands B.V., registered in The Netherlands under 33264294. 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 Rafanana Israel	Design Development Software
Analogic Corporation 8 Centennial Drive Peabody Massachusetts 01960 USA	Design Manufacture

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Page 1 of 7

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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
Carestream Health France 1, rue Gallée 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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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
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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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
Carestream Health, Inc. 8124 Pacific Avenue White City Oregon 97503 USA	Manufacture
Carestream Health, Inc. Global R & D Center (Shanghai) No. 27 Xinjingqiao Road Shanghai 201206 China	Design Development
Communication & Power Industries Canada Inc. 45 River Drive Georgetown Ontario L7G 2J4 Canada	Manufacture

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Page 4 of 7

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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
Micro-X Ltd 1284 South Road Clovell Park South Australia 5042 Australia	Design Manufacture
Rayco (Shanghai) Medical Products Company Limited Building 7, No. 1510 Chuangqiao Road China (Shanghai) Pilot Free Trade Z Shanghai 201206 China	Manufacture

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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

Rayco (Xiamen) Medical Products
Company Limited
308 Wengjiao Road
Haicang District
Xiamen
Fujian
361022
China

Manufacture

ScImage, Inc.
4916 El Camino Real, Suite 200
Los Altos
California
94022
USA

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Software**

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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

Soluciones Médicas Exportación
S de RL de CV
Calle Anillo Periferico Poniente No. 3100
Colonia Paraisos 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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Page 7 of 7



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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

Page: 1 of 2



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An electronic certificate can be authenticated [online](http://www.bsigroup.com/Certificates). Printed copies can be validated at www.bsigroup.com/Certificates.
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

Effective Date: 2019-10-03

Latest Revision Date: 2019-09-24

Expiry Date: 2022-10-02

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