



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/ClientDirect). Printed copies can be validated at www.bsigroup.com/ClientDirect.
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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A Member of the BSI Group of Companies.



EC Certificate - Full Quality Assurance System

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

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, dental digital imaging software, 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 0086):

Amee

Frank Lee, EMEA Compliance & Risk Director

First Issued: **06 March 1996**

Date: **10 February 2016**

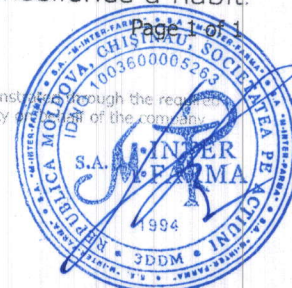
Expiry Date: **05 March 2021**

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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 or parties other than the company named on this certificate, unless specifically agreed with RS1.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 845 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
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: **10 February 2016**
Issued To: **Carestream Health, Inc.**
150 Verona Street
Rochester
New York
14608
USA

Subcontractor:	Service(s) supplied
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
Carestream Dental LLC 1765 The Exchange Atlanta Georgia 30339 USA	Design Development

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EC Certificate - Full Quality Assurance System

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

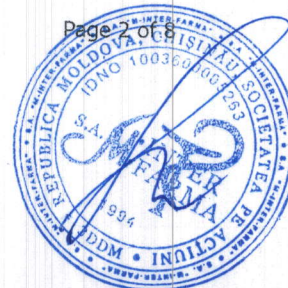
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Issued To: **Carestream Health, Inc.
150 Verona Street
Rochester
New York
14608
USA**

Subcontractor:	Service(s) supplied
Carestream Health France 1, rue Galilée 93192 NOISY-LE-GRAND CEDEX France	EU Representative
Carestream Health, Inc. 1049 West Ridge Road Rochester New York 14615 USA	Design Development Manufacture
Carestream Health, Inc. 1669 Lake Avenue Rochester New York 14652 USA	Design Development Manufacture

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EC Certificate - Full Quality Assurance System

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Rochester
New York
14608
USA

Subcontractor:	Service(s) supplied
Carestream Health, Inc. Global R & D Center (Shanghai) No. 27 Xinjinqiao Road Shanghai 201206 China	Design Development
Carestream Health, Inc. 5450 Campus Drive Canandagula New York 14424 USA	Manufacture
Carestream Health Ltd. Hacarmel 3A Star Yokneam Building P.O. Box 505 2069204 Yokneam Israel	Design Manufacture

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150 Verona Street
Rochester
New York
14608
USA

Subcontractor:	Service(s) supplied
Communication & Power Industries Canada Inc. 45 River Drive Georgetown Ontario L7G 2J4 Canada	Manufacture
Quantum Medical Imaging, LLC 2002-B Orville Drive North Ronkonkoma New York 11779 USA	Manufacture

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150 Verona Street
Rochester
New York
14608
USA

Subcontractor:

Service(s) supplied

Rayco (Shanghai) Medical Products
Company Limited
Building 7, No. 1510 Chuangqiao Road
Jinqiao Export Processing Zone
Pudong New Area
Shanghai
201206
China

Manufacture

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

Manufacture

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150 Verona Street
Rochester
New York
14608
USA

Subcontractor:	Service(s) supplied
Sanmina-SCI Israel Medical Systems Ltd Zone 5, Korean Industrial Park 24952 Maalot Israel	Design Manufacture
ScImage, Inc. 4916 El Camino Real, Suite 200 Los Altos California 94022 USA	Design Development Software
Soluciones Médicas Exportación S de RL de CV Prolongación Mariano Otero 408 Ciudad del Sol, 45050 Zapopan Jalisco Mexico	Manufacture

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150 Verona Street
Rochester
New York
14608
USA

Subcontractor:	Service(s) supplied
Trophy 4 rue F. Pelloutier Croissy-Beaubourg 77435 Marne-la-Vallée Cedex 2 France	Design Development EU Representative Manufacture
Varian Medical Systems, Inc. X-Ray Products 1678 South Pioneer Road Salt Lake City Utah 84104 USA	Manufacture

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SERTİFİKA CERTIFICATE

BEREN MEDİKAL PAZARLAMA SAN. TİC. LTD. ŞTİ.

İOSB FATİH SAN SİT 3B BLOK NO:3-4 BAŞAKŞEHİR / İSTANBUL

MEDİKAL KAYIT KAĞITLARI VE ULTRASON PRİNTER KAĞITLARI TASARIMI VE ÜRETİMİ, YOĞUN
BAKIM CİHAZLARI KURULUM, MONTAJ VE TEKNİK SERVİSİ

PRODUCTION AND SALES OF MEDICAL RECORD & CHART PAPERS, ULTRASOUND IMAGING
PAPERS, INSTALLATION AND AFTERSALES TECHNICAL SERVICES OF INTENSIVE CARE DEVICES

kapsamında
with a scope of

ISO 13485:2016

Tıbbi Cihazlar Kalite Yönetim Sistemine uygun bir sistem kurmuştur.
has established that is in compliance with the Medical Devices Quality Management System Standard.

Sertifika No : MDD1024

Certificate No

İlk Yayın Tarihi : 19.07.2019

Initial Date

Sertifika Yayın Tarihi / Rev No : 19.07.2019/00

Date of This Certificate / Rev.No

Sertifika Geçerlilik Tarihi : 18.07.2020

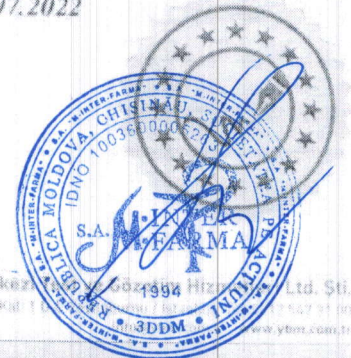
Certificate Expiry Date

Yeniden Belgelendirme Tarihi : 18.07.2022

Date of Re-Certification

Zühtü Özdemir
GENEL MÜDÜR
General Manager

Özdemir



Bu belge YBM'nin belgelendirme kurallarına uyulması ve periyodik ara denetimlerin
başarıyla tamamlanması kaydıyla geçerlidir. Daha fazla bilgi için lütfen bizi arayınız.
This certificate is effective if it is complied with the certification rules of YBM and periodic
surveillance audits are completed successfully. Please call us for more information.

Yönetim Belgelendirme Merkez... S.A. FARMASİYERLERİ Ltd. Şti.
Tehiz Mah. Göt Sok. No:11 Kat:1 T.C. ... 3DDM ... www.ybm.com.tr