Carestream

Digitally signed by Ungureanu Anatolie
Date: 2019.01.18 11:09:10 EET
Reason: MoldSign Signature
Location: Moldova

DECLARATION OF CONFORMITY

Carestream Health, Inc., hereby declares under its sole responsibility that the product(s) listed are made in conformity with ANNEX I, Essential Requirements and ANNEX VII, EC Declaration of Conformity, of the European Economic Community Medical Device Directive, [Directive 93/42/EEC], and the requirements of Clause 6.6 of Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002 relating to the stated devices.

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 DVM Mammography Laser Imaging Film
DRYVIEW DVM+ Mammography Laser Imaging Film
"End of List"

Device Classification: Class I, Rule I (Council Directive 93/42/ EEC. ANNEX IX)
Class I, Schedule 2, Part 2 Rule 2.1 (Australian Therapeutic Goods (Medical Devices) Regulations 2002)

GMDN Code and Term: 40980. X-ray film, diagnostic imaging, medical 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.

European Authorized Representative: Carestream Health France
1, rue Galilée
93192 NOISY-LE-GRAND CEDEX
FRANCE

VENCIUR REZERVĂ SA «1995»

Standards Applied:

EN ISO 13485:2012	Medical devices – Quality management systems – Requirements for regulatory purposes
ISO 13485: 2003	Medical devices – Quality management systems – Requirements for regulatory purposes
EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN 980:2008	Symbols for use in the labeling of medical devices
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 4090:2004	Photography – Medical radiographic cassettes / screens / films and hard-copy imaging films – Dimensions and specifications
EN 62366:2008	Medical devices - Application of usability engineering to medical devices

Robert C. Meagher
Director
International Regulatory Affairs
Carestream Health, Inc.
150 Verona Street
Rochester, New York 14608
Telephone 585-627-6528

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003

This is to certify that:

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

Holds Certificate No: **FM 72498**

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 for the following scope:

The design, manufacture, distribution, (integration, installation and servicing excluding film products) of diagnostic image recording devices, photo chemicals, medical dental imaging systems, 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:

Carlos Pitanga, SVP, System Certification and Compliance

Original Registration Date: 12/20/2002 Effective Date: 10/19/2016 Expiry Date: 02/28/2019

CMDCAS Recognized Registrar

SCC Accredited CB-MS OCSM Accrédité CCN

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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, 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):

Frank Lee, EMEA Compliance & Risk Director

First Issued: **06 March 1996** Date: **10 February 2016** Expiry Date: **05 March 2021**

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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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Date:	**10 February 2016**
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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Subcontractor:	**Service(s) supplied**
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**
Carestream Health, Inc. 8124 Pacific Avenue White City Oregon 97503 USA	**Manufacture**

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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 Canandaguia New York 14424 USA	**Manufacture**
Carestream Heath Ltd. Hacarmel 3A Star Yokneam Building P.O. Box 505 2069204 Yokneam Israel	**Design** **Manufacture**

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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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Subcontractor:	**Service(s) supplied**
Rayco (Shanghai) Medical Products Company Limited Building 7, No. 1510 Chuanqiao 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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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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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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America

CERTIFICATE

No. QS5 17 06 84658 008

Certificate Holder: **Rayco (Shanghai) Medical Products Company Limited**
Building 7, No.1510 Chuanqiao Road
China (Shanghai) Pilot Free Trade Zone
201206 Shanghai
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of Imaging Systems & Accessories**

Standard(s): **ISO 9001:2015**

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

Report No.: **M2435**

Effective Date: **2017-06-19**
Expiry Date: **2020-07-20**

Earl Buckmiller
Director, Quality Systems & MS Cert. Body

TÜV SÜD America Inc.
10 Centennial Drive
Peabody, MA 01960
USA

SCC Accredited CB-MS OCSM Accrédité CCN

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CERTIFICATE

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PEOPLE'S REPUBLIC OF CHINA

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PEOPLE'S REPUBLIC OF CHINA

Production and Distribution of Imaging Systems & Accessories

Effective Date: 2017-06-19
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Earl Buckmiller
Director, Quality Systems & MS Cert. Body

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10 Centennial Drive
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