

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):



Gary E Slack, Senior Vice President Medical Devices

First Issued: 1996-03-06**Date: 2019-12-16****Expiry Date: 2024-05-26**

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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.

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Supplementary Information to CE 01233

Issued To:

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NBOG code(s)	Device Description	Intended Purpose
Class IIb		
MD 1201, MDS 7010	Diagnostic X-Ray Systems (Digital Radiography)	For general radiographic imaging (with a digital imaging system incorporated)
MD 1201, MDS 7010	Diagnostic X-Ray Systems (Analogue Radiology)	For general radiographic imaging
MD 1201, MDS 7010	Diagnostic X-Ray Systems (Computed Tomography)	For x-ray computed tomography and projection x-ray imaging of upper and lower extremities
Class IIa		
MD 1202	Storage Phosphor Screens & Cassettes for Computed Radiography	N/A for Class IIa devices
MD 1202	X-Ray Films (Sheet & Dental)	N/A for Class IIa devices
MD 1202	Digital Imaging Systems (Digital Flat Panel Detectors)	N/A for Class IIa devices
MD 1202	Computed Radiography Readers (Storage Phosphor Readers)	N/A for Class IIa devices
MD 1111	PACS Software	N/A for Class IIa devices
Class Im		
MD 1111	PACS Software	N/A for Class Im devices

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List of Significant Subcontractors

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

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Subcontractor:	Service(s) supplied
Agfa-Gevaert HealthCare GmbH Bürgermeister-Götz-Str. 10 86529 Schrobenhausen Germany	Manufacture
Algotec Systems Ltd 2 Hapnina Street 43107 Ra'anana Israel	Design Development Software
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

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Subcontractor:	Service(s) supplied
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
Carestream Health, Inc. 2000 Howard Smith Avenue West Windsor Colorado 80550 USA	Manufacture

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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 Xinqiniao Road Shanghai 201206 China	Design Development
iRay Technology Taicang Ltd. No. 33 Xingang Road Taicang Port Economic and Technological Development Zone Taicang 215434 Jiangsu China	Manufacture

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Subcontractor:

Service(s) supplied

Micro-X Ltd
 1284 South Road
 MAB Gate 2
 Tonsley
 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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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

**Design
 Development
 Software**

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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

Varex Imaging Corporation
 X-Ray products
 1678 South Pioneer Road
 Salt Lake City
 Utah
 84104
 USA

Manufacture

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