

# 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 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: **2020-10-29**

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

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NBOG code(s)	Device Description	Intended Purpose
<b>Class IIb</b>		
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
<b>Class IIa</b>		
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	Image Suite software (Mini-PACS)	N/A for Class IIa 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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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Agfa-Gevaert HealthCare GmbH Bürgermeister-Götz-Str. 10 86529 Schrobenhausen Germany	<b>Manufacture</b>
Carestream Health France SAS 207 Rue de Bercy 75012 Paris France	<b>EU Representative</b>
Carestream Health, Inc 5450 Campus Drive Canandaigua New York 14424 USA	<b>Manufacture</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Carestream Health, Inc. 1049 West Ridge Road Rochester New York 14615 USA	<b>Design Development Manufacture</b>
Carestream Health, Inc. 1669 Lake Avenue Rochester New York 14652 USA	<b>Design Development Manufacture</b>
Carestream Health, Inc. 2000 Howard Smith Avenue West Windsor Colorado 80550 USA	<b>Manufacture</b>

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**USA**

<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Carestream Health, Inc. 8124 Pacific Avenue White City Oregon 97503 USA	<b>Manufacture</b>
Carestream Health, Inc. Global R & D Center (Shanghai) No. 27 Xinjinqiao Road Shanghai 201206 China	<b>Design Development</b>
iRay Technology Taicang Ltd. No. 33 Xinggang Road Taicang Port Economic and Technological Development Zone Taicang 215434 Jiangsu China	<b>Manufacture</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Micro-X Ltd 1284 South Road MAB Gate 2 Tonsley South Australia 5042 Australia	<b>Design</b> <b>Manufacture</b>
Rayco (Shanghai) Medical Products Company Limited Building 7, No. 1510 Chuanqiao Road China (Shanghai) Pilot Free Trade Z Shanghai 201206 China	<b>Manufacture</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Rayco (Xiamen) Medical Products Company Limited 308 Wengjiao Road Haicang District Xiamen Fujian 361022 China	<b>Manufacture</b>
Soluciones Médicas Exportación S de RL de CV Calle Anillo Periferico Poniente No. 3100 Colonia Paraísos Del Colli Zapopan Jalisco 45069 Mexico	<b>Manufacture</b>

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**Subcontractor:**

**Service(s) supplied**

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

**Manufacture**

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