



# 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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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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## List of Significant Subcontractors

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

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Date: **2019-02-27**  
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**14608**  
**USA**

<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Agfa-Gevaert HealthCare GmbH Bürgermeister-Götz-Str. 10 Schrobenhausen 86529 Germany	<b>Manufacture</b>
Algotec Systems Ltd 2 Hapnina Street PO BOX 46 43107 Ra'anana Israel	<b>Design</b> <b>Development</b> <b>Software</b>
Analogic Corporation 8 Centennial Drive Peabody Massachusetts 01960 USA	<b>Design</b> <b>Manufacture</b>

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**USA**

<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Carestream Health France 1, rue Galilée 93192 NOISY-LE-GRAND CEDEX France	<b>EU Representative</b>
Carestream Health, Inc 5450 Campus Drive Canandaigua New York 14424 USA	<b>Manufacture</b>
Carestream Health, Inc. 1049 West Ridge Road Rochester New York 14615 USA	<b>Design Development Manufacture</b>

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**USA**

<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Carestream Health, Inc. 1669 Lake Avenue Rochester New York 14652 USA	<b>Design</b> <b>Development</b> <b>Manufacture</b>
Carestream Health, Inc. 1964 Lake Ave Rochester New York 14615 USA	<b>Design</b>
Carestream Health, Inc. 2000 Howard Smith Avenue West Windsor Colorado 80550 USA	<b>Manufacture</b>

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<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 Xinqiniao Road Shanghai 201206 China	<b>Design Development</b>
Communication & Power Industries Canada Inc. 45 River Drive Georgetown Ontario L7G 2J4 Canada	<b>Manufacture</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Micro-X Ltd 1284 South Road Clovelly Park 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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**Subcontractor:**

**Service(s) supplied**

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

**Manufacture**

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

**Design  
Development  
Software**

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<b>Subcontractor:</b>	<b>Service(s) supplied</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>
Varian Medical Systems, Inc. X-Ray Products 1678 South Pioneer Road Salt Lake City Utah 84104 USA	<b>Manufacture</b>

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