



## DECLARATION OF CONFORMITY

Carestream Health, Inc., hereby declares that the product(s) listed are made in conformity with:  
Medical Device Directive [Directive 93/42/EEC], ANNEX II Conformity Assessment Procedure, Directive on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment [Directive 2011/65/EU], Directive on the harmonization of the laws of the Member States relating to the making available on the market of radio equipment [Directive 2014/53/EU] and the Australian Therapeutic Goods (Medical Devices) Regulations 2002, Clause 1.8 of Schedule 3

Manufacturer's Name and Address: Carestream Health, Inc.  
150 Verona Street  
Rochester, New York, USA 14608

Medical Device: Diagnostic X-Ray System

Product List: DRX-Compass X-ray System  
CARESTREAM DRX-Evolution Plus  
—End of List—

Device Classification: Europe - Class IIb, ANNEX IX, Rule 10  
Australia - Class IIb, Schedule 2, Part 4, Rule 4.3 (3b)

GMDN Code and Term: 37645 X-ray system, general-purpose, stationary, digital

Scope of Application All declared products

Each kind of medical device to which the quality-management system has been applied complies with the applicable provisions of the essential principles, the classification rules, and the full-quality-assurance procedures at each stage, from the design of the device until its final inspection before being supplied.

Quality-Management-System Certified to EN ISO 13485 by:  
TUV No. QS2 084658 0010 Rev 01  
BSI No. FM 701584

European Notified Body: British Standards Institute, BSI (2797)

Full-Quality-Assurance-System  
Certificate (CE): BSI Certificate Number CE 01233

European Authorized Representative: Carestream Health France SAS  
207, Rue de Bercy  
75012 Paris  
France

The relevant sections of the following European Union Harmonized standards apply to the listed product(s):

EN ISO 14971

EN ISO 15223-1

EN 1041

EN 62304

EN 60601-1

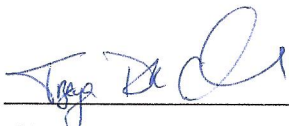
EN 60601-1-2

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EN 55011

EN 50581

EN 62321



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