Carestream

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:	Digital Imaging System
Product List:	DRX 2530C Detector DRX Plus 2530C Detector DRX Plus 3543 Detector DRX Plus 3543C Detector DRX Plus 4343 Detector DRX Plus 4343C Detector DRX Plus 4343F Detector DRX Plus 4343FC Detector DRX Core 3543 Detector DRX Core 3543C Detector DRX Core 4343 Detector DRX Core 4343C Detector DRX Core 4343F Detector DRX Core 4343FC Detector TRIMAX 3543 Detector TRIMAX 3543C Detector TRIMAX 4343 Detector TRIMAX 4343C Detector TRIMAX 4343F Detector TRIMAX 4343FC Detector TRIMAX 35C Detector TRIMAX 43C Detector Focus 35C Detector Focus 43C Detector Lux 35 Detector
Device Classification:	Europe - Class IIa, ANNEX IX, Rule 16 Australia - Class IIa, Schedule 2, Part 4.3(2)(c)
GMDN Code and Term:	61108, Indirect flat panel x-ray detector
Scope of Application	All declared products

Each kind of medical device to which the Full Quality Assurance Procedures have been applied complies with the applicable provisions of the essential principles, the classification rules, 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 BSI No. FM 701584 Certified to EN ISO 13485 by TUV Rheinland No. SX 60134204 0001 (iRay)
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):

European Union Harmonized standards apply to the listed product(s):

ISO 13485

EN ISO 14971

EN ISO 15223

EN 1041

EN 60601-1

EN 60601-1-2

EN 50581

EN 55011

EN 62321

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