Carestream

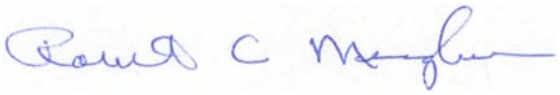
DECLARATION OF CONFORMITY

Carestream Health, Inc., hereby declares under its sole responsibility that the products listed are made in conformity with ANNEX I, Essential Requirements, and ANNEX II, EC Declaration of Conformity (Full quality assurance system), of the European Economic Community Medical Device Directive, [Directive 93/42/EEC]; ANNEX I, Essential Health and Safety Requirements of the Directive on Machinery [Directive 2006/42/EC]; and Article 4 of the Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment [Directive 2011/65/EU].

MANUFACTURER'S NAME AND ADDRESS:	Carestream Health, Inc. 150 Verona Street Rochester, New York, USA 14608
Medical Device:	Dental X-ray Systems
Product List:	CS 9300 CS 9300 Select CS 9000 CS 9000 3D "End of List"
Device Classification:	Class IIb, Rule 10 (Council Directive 93/42/EEC, ANNEX IX)
GMDN Code and Term:	45855, Stationary extraoral dental x-ray system, digital
Scope of Application:	All declared products
Quality Management System Certificate:	GMED Certificate No. 7908
European Notified Body:	British Standards Institute, BSI (ID: 0086)
Full Quality Assurance System Certificate:	BSI Certificate No.01233
European Authorized Representative:	Trophy 4, Rue F. Pelloutier Croissy-Beaubourg 77435 Marne-la-Vallee, Cedex 2 France

Standards Applied:

EN ISO 13485: 2012	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes.
EN ISO 14971: 2012	Medical Devices – Application of Risk Management to Medical Devices.
EN 60601-1: 2006	Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance.
EN 60601-1-2: 2007	Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.
EN 60601-1-3: 2008	Medical Electrical Equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral standard: Radiation protection in diagnostic X-ray equipment.
EN 60601-2-28: 2010	Medical Electrical Equipment – Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis.
EN 62304: 2006	Medical Device Software – Software life cycle processes.
EN 60601-1-6: 2010	Medical Electrical Equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
EN 62366: 2008	Medical Devices – Application of usability engineering to medical devices.
EN ISO 10993-1: 2009 AC: 2010	Biological evaluation of medical devices – Part 1: Evaluation and Testing within a risk management process.
EN 980: 2008	Symbols for Use in the Labeling of Medical Devices.
EN 1041: 2008	Information supplied by the manufacturer of medical devices.
EN 50581: 2012	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances.
EN 62321: 2009	Electrotechnical products – Determination of level of six regulated RoHS substances.
EN 62474: 2012	Material Declarations for products of and for the electrotechnical industry.



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World Wide Regulatory Affairs
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