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DECLARATION OF CONFORMITY

Carestream Health, Inc., hereby declares under its sole responsibility that the product listed is 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 St. Rochester, New York, 14608 USA
Medical Device:	Dental X-ray Systems
Product List:	CS 2100 CS 2200 "End of List"
Device Classification:	Class IIb, Rule 10 (Council Directive 93/42/EEC, ANNEX IX)
GMDN Code and Term:	42297, Stationary intraoral dental x-ray system, digital
Scope of Application:	All declared products
Quality Management System Certificate:	GMED Certificate No. 7908
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

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Standards Applied	
EN ISO 13485:2012	Medical devices – Quality Management Systems – Requirements for regulatory purposes.
ISO 9001:2008	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: 1990 Al: 1993/A2:1995	Medical Electrical Equipment -Part 1 -General requirements for Safety.
EN 60601-1-2:2001 A1:2006	Medical electrical equipment -Part 1-2: General requirements for safety. Collateral standard: Electromagnetic compatibility -Requirements and tests.
EN 60601-1-3:1994	Medical Electrical Equipment -Part 1-3: General requirements for Safety- Collateral Standard: General requirements for radiation protection in diagnostic X-ray equipment.
EN 60601-1-4:1996 Al: 1999	Medical Electrical Equipment - Part 1-4: General requirements for safety – Collateral Standard: Programmable electrical medical systems.
EN 60601-1-6: 2004	Medical Electrical Equipment -Part 1-6: General requirements for safety- Collateral Standard: Usability.
EN 60601-2-7:1998	Medical electrical equipment. Part 2-7: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators.
EN 60601-2-28: 1993	Medical electrical equipment. Part 2-28: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis.
EN 62304: 2006	Medical device software – Software life cycle processes.
EN 980: 2008	Symbols for Use in the Labeling of Medical Devices.
EN 1041: 2008	Information supplied by the manufacturer with medical devices.
EN 50581: 2012	Technical documentation for the assessment of electrical and electronic produ 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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