Carestream Dental LLC
3625 Cumberland Boulevard, Suite 700,
Atlanta, GA USA 30339

DECLARATION OF CONFORMITY

Carestream Dental LLC, 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 Dental LLC 3625 Cumberland Boulevard, Suite 700, Atlanta, GA USA 30339
Medical Device:	Dental X-ray Systems
Product List:	CS 8200 3D CS 8200 3D Select CS 8200 3D Access "End of List"
Device Classification:	Class IIb, Rule 10 (Council Directive 93/42/EEC, ANNEX IX)
GMDN Code and Term:	61019, Cone bam computed tomography system, head/neck 43620, Stationary cephalometric 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: 2797)
Full Quality Assurance System Certificate:	BSI Certificate No. 676550
European Authorized Representative:	Trophy 4, Rue F. Pelloutier Croissy-Beaubourg 77435 Marne-la-Vallée, Cedex 2 France

Standards Applied

EN ISO 13485: 2016	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 / A1: 2013	Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance.
EN 60601-1-2: 2015	Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests.
EN 60601-1-3: 2008 / A11: 2016	Medical Electrical Equipment – Part 1-3: General requirements for basic and safety essential performance – Collateral standard: Radiation protection in diagnostic X-ray equipment.
EN 60601-2-63: 2015	Medical Electrical Equipment – Part 2-63: Particular requirements for the basic and safety essential performance of dental extra-oral equipment.
EN 62304: 2006 / AC: 2008	Medical Device Software – Software life cycle processes.
EN 60601-1-6: 2010 / A1: 2015	Medical Electrical Equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability.
EN 62366: 2008 / A1: 2015	Medical Devices – Application of usability engineering to medical devices.
EN 10993-1: 2009 / AC: 2010	Biological evaluation of medical devices – Part 1: Evaluation and Testing within a risk management process.
EN ISO 15223-1: 2016	Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.
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.

Marie-Pierre Labat-Camy
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