Carestream

DECLARATION OF CONFORMITY

Carestream Health, Inc., hereby declares under its sole responsibility that the product(s) 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]; Article 4 of the Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment [Directive 2011/65/EU] and the ANNEX I, Essential Health and Safety Requirements of the Directive on Machinery [Directive 2006/42/EC]

Manufacturer's Name and Address:	Carestream Health, Inc. 150 Verona Street Rochester, New York 14608 USA
Medical Device:	Dental X-ray Systems
Product List:	CS 8100 3D CS 8100 3D Access "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 Number 7908
European Notified Body:	British Standards Institute, BSI (0086)
Full Quality Assurance System Certificate:	BSI Certificate Number CE 01233
European Authorized Representative:	Carestream Health France 1, rue Galilée 93192 NOISY-LE-GRAND CEDEX 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 980: 2008	Symbols for use in the labeling of medical devices
EN 1041: 2008	Information supplied by the manufacturer with 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 50581 : 2012	Technical documentation for the assessment of electrical and electric products with respect to the restriction of hazardous substances
EN 62321 : 2009	Electrotechnical products - Determination of levels of six regulated RoHS substances (lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, polybrominated diphenyl ethers)
EN 62474 : 2012	Material Declarations for products of and for the electrotechnical industry

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