Carestream HEALTH

DECLARATION OF CONFORMITY

Carestream Health, Inc., hereby declares under its sole responsibility that the product(s) listed are made in accordance with ANNEX I, Essential Requirements, ANNEX II, EC Declaration of Conformity (Full quality assurance system) [EC 93/42/EEC] of the European Economic Community Medical Device Directive and the Essential Principal requirements of Clause 1.8 of Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations.

Manufacturer's Name:	Carestream Health, Inc. 150 Verona Street Rochester, New York, USA 14608
Medical Device:	Dental X-ray Systems
Product List:	KODAK 9500 Cone Beam 3D System "End of List"
Device Classification:	Class IIb, Rule 10 (Council Directive 93/42/EEC, ANNEX IX) Class IIb, Rule 4.3 (Australian Therapeutic Goods (Medical Devices) Regulations 2002)
GMDN Code and Term:	37640, X-ray system, Diagnostic, Dental, Panoramic, Digital
UMDNS Code:	18056, Radiographic Systems, Digital, Dental
Scope of Applications:	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.

Full Quality Management System Certificate:	GMED No.1298 / 9001 – 13485 / 1
Design Examination Certificate:	BSI Certificate Number CE 01233
European Authorized Representative:	Trophy 4, Rue F. Pelloutier Croissy-Beaubourg 77 435 Marne-la-Vallee, Cedex 2, France

The reference product{s) and/or their components conform, at a minimum, to the following standard{s) and/or other equivalent normative document{s), pursuant to the provisions of the European Economic Community Medical Device Directive, and the Australian Therapeutic Goods (Medical Devices) Regulations:

NF EN ISO 13485:2004	Medical Devices – Quality Management Systems -Requirements for Regulatory Purposes
ISO 9001:2000	Quality Management Systems - Requirements
EN 60601-1: 1990 Al:1993/A2:1995	Medical Electrical Equipment -Part 1 -General requirements for Safety
EN 60601-1-2:2007	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 I -General requirements for Safety-Collateral Standard -General requirements for radiation protection in diagnostic X-ray equipment
EN 60601-1-4:1996 Al:1999	General requirements for safety-4 -Collateral Standard: Programmable electrical medical systems
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: particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis

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