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 VII, EC Declaration of Conformity, 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 requirements of Clause 6.6 of Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002 relating to the stated devices.

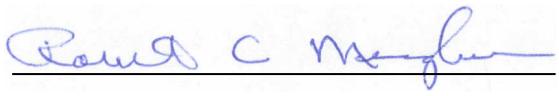
Manufacturer's Name and Address:	Carestream Health, Inc. 150 Verona Street Rochester, New York USA, 14608
Medical Device:	Intra-oral scanner
Product List:	CS 3500 "End of List"
Device Classification:	Class I, Rule 5 (Council Directive 93/42/ EEC, ANNEX IX) Class I, Schedule 2, Part 4, Rule 4.1 (Australian Therapeutic Goods (Medical Devices) Regulations 2002)
GMDN Code and Term:	38597 CAD/CAM Unit, dental, chairside
Scope of Application:	All Declared Products

Each kind of medical device to which the Declaration of Conformity (not requiring assessment by the Secretary) procedures have been applied complies with the applicable provisions of the essential principles and the classification rules before being supplied.

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 980:2008	Symbols for use in the labeling of medical devices
EN 1041:2008	Information supplied by the manufacturer of 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: 2007/AC: 2010	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
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 62304: 2006/AC: 2008	Medical device software – Software life-cycle processes
EN 62471: 2008	Photobiological safety of lamps and lamp systems
EN ISO 17664: 2004	Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable 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 electronic products with respect to the restriction of hazardous substances
EN 62321: 2009	Electrotechnical products – Determination of levels of six regulated substances (lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, polybrominated diphenyl ethers)
EN 62474: 2012	Material declaration for products of and for the electrotechnical industry



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