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, General Safety and Performance Requirements, and ANNEX IV, EU Declaration of Conformity of the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical device; 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
SRN of the Manufacturer	US-MF-000003727
Medical Device:	Dental video Camera
Product and Trade name:	CS 1200 "End of List"
Basic UDI-DI:	01921551200GL
Device Classification:	Class I, Rule 5 (Regulation EU 2017/745, ANNEX VIII)
EMDN Code:	Z121101 - INSTRUMENTS FOR DENTAL TREATMENT UNITS
GMDN Code and Term:	45099, Flexible video stomatoscope
Scope of Application:	All Declared Products
European Authorized Representative:	Trophy 4, Rue F. Pelloutier Croissy-Beaubourg 77435 Marne-la-Vallée, Cedex 2 France
SRN of the European authorized representative:	FR-AR-000001797

Standards Applied

EN ISO 13485: 2016	Medical devices – Quality management systems – Requirements for

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	regulatory purposes
EN ISO 14971: 2019	Medical devices – Application of risk management to medical devices
EN ISO 15223-1: 2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirement
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: 2015	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
IEC 60601-1-6: 2010 / A1: 2013 / A2: 2020	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 62366-1: 2015 / A1: 2020	Medical Devices – Part 1: Application of usability engineering to medical devices
IEC 62304: 2006 / A1: 2015	Medical device software — Software life cycle processes
EN 62471: 2008	Photobiological safety of lamps and lamp systems
EN ISO 10993-1: 2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
EN 63000: 2018	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
EN 50581: 2012	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

Marie-Pierre Labat-Camy
Global Regulatory Affairs Senior Manager