



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 IX chapters I & III, Conformity assessment based on a quality management system and assessment of the technical documentation, of the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical device; 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

SRN of the Manufacturer US-MF-000003727

Medical Device: Dental X-Ray Systems

Product and Trade name: CS 8100  
CS 8100 Access  
"End of List"

Intended purpose: The CS 8100 Family are intended to produce complete or segmented tomographic digital panoramic X-ray images to be used at the direction of health care professionals of the dento-maxillofacial region of the human anatomy as diagnostic support for pediatric and adult patient.

Basic UDI-DI: 01921558100HY

Device Classification: Class IIb, Rule 10 (Regulation EU 2017/745, ANNEX VIII)

EMDN Code: Z110303, Instruments for Orthopantomography and panoramic dental radiology

GMDN Code and Term: 45855, Stationary extraoral dental 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. MDR 755277

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

Issuance date September 15, 2022, Revision Number A, (CS 8100), English

GTEMP-0185 Rev3

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#### Standards Applied

EN ISO 13485: 2016/A11:2021	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes.
EN ISO 14971: 2019/A11: 2021	Medical Devices – Application of Risk Management to Medical Devices.
EN 60601-1: 2006 / A2: 2021	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
EN 60601-1-2:2015/A1:2021	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/A2:2021	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment.
EN 60601-2-63:2015/A2:2021	Medical electrical equipment - Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment.
EN 62304:2006/A1:2015	Medical device software - Software life-cycle processes
EN 60601-1-6:2010/A2:2021	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.
EN 62366-1: 2015/A1: 2020	Medical Devices - Part 1: Application of usability engineering to medical devices.
EN ISO 15223-1: 2021	Medical Devices – Symbols to be used with medical devices labels, labeling and information to be supplied – Part 1: General requirements.
EN ISO 20417: 2021	Medical devices - Information to be supplied by the manufacturer
EN 50581: 2012	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances.
EN IEC 63000:2018	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances.

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