Carestream Dental LLC
3625 Cumberland Boulevard, Suite 700
Atlanta, GA USA 30339

DECLARATION OF CONFORMITY

I, as Executive Director RA/QA/EHS, Carestream Dental LLC, hereby declare that the below mentioned medical device

(i) complies with all the requirements under the Act;
(ii) has been classified according to the classification rules as specified in First Schedule on Rules of Classification of Medical Devices; and
(iii) conforms to requirements specified in APPENDIX 1 of the Third Schedule on Essential Principles for Safety and Performance of Medical Devices under Medical Devices Regulations 2012.

(A) Particulars of medical device(s)

Generic name:	Intraoral Scanner
Specified name:	CS 3700
Brand/Model:	Carestream Dental
Manufacturer:	Carestream Dental LLC 3625 Cumberland Boulevard, Suite 700 Atlanta, GA USA 30339
Country of Origin:	France
Manufacturing site:	Rayco (Shanghai) Medical Products Company Limited Building 7, No. 1510 Chuanqiao Road China (Shanghai) Pilot Free Trade Zone 201206 Shanghai People's Republic of China
Risk-based classification:	Class A
Classification rule:	5
GMDN code:	38597 Dental CAD/CAM system, chairside

Medical device registration number or any approval code:

Australia	ARTG 318700
EU	CE 676550

(B) Quality Management System Certificate ("QMS")

Conformity Assessment Body issuing the certificate: TÜV SÜD

Certificate number:	QS2 17 06 84658 009
Issuance date:	June 19, 2017
Expiry date:	July 20, 2020

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(C) Standards Applied

EN ISO 13485: 2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes.
EN ISO 14971: 2012	Medical Devices – Application of Risk Management to Medical Devices.
EN ISO 15223-1: 2016	Medical devices - Symbols to be used with medical devices labels, labeling and information to be supplied - Part I: General requirements
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.
EN 62471: 2008	Photobiological safety of lamps and lamp system
EN ISO 17664: 2017	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices
EN 62304: 2006/A1: 2015	Medical Device Software – Software life cycle processes.
EN 62366: 2008	Medical Devices – Application of usability engineering to medical devices.
EN 60601-1-6: 2010	Medical Electrical Equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
EN ISO 10993-1: 2018	Biological evaluation of medical devices - Part I: Evaluation and testing within a risk management process

I am fully responsible with all the information provided in this declaration. This declaration of conformity is valid from 6 February 2020.

I fully understand and acknowledge that it is an offence under Section 76 of the Medical Device Act 2012 [Act 737] to make, sign or furnish any declaration, certificate or other document which is untrue, inaccurate or misleading.

Authorized Signatory:

Marie-Pierre Labat-Camy
Global Regulatory Senior Manager

February 12, 2020
Date