EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 755277 R000

Manufacturer: Carestream Dental LLC

Address:
3625 Cumberland Boulevard, Suite 700
Atlanta
Georgia
30339
USA

Single Registration Number: US-MF-000003727

EU Authorised Representative: Trophy

Address:
4 rue F. Pelloutier
Croissy-Beaubourg
77435 Marne-la-Vallée Cedex 2
France

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb implantable devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2022-09-15**

Current Issue Date: **2022-09-15**

Starting Validity Date: **2022-09-15**

Expiry Date: **2027-09-14**

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Device Schedule: Class IIb devices

Class IIb	Intended purpose
Dental Extra-oral X-ray System	To produce two-dimensional and three-dimensional digital X-ray images of the dento-maxillo-facial area, ENT (Ear, Nose, and Throat), cervical spine, and wrist regions, for pediatric and adult patients.
Dental Intra-oral X-Ray Equipment	For dental radiographic examination and diagnostic of the teeth, jaw, and oral structures of the dento-maxillo-facial area.

Device Schedule: Class IIa devices

Device(s)	Risk Classification
Dental Digital Imaging Software	Class IIa
Digital Dental X-Ray Instrument	Class IIa

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3497497	Issued

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

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List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

MDR 755277 R000

Date: **2022-09-15**

Critical Subcontractor/Crucial Supplier	Service(s) supplied
Afga-Gevaert HealthCare GmbH Bürgermeister-Götz-Str. 10 86529 Schrobenhausen Germany	**Manufacture**
Rayco (Shanghai) Medical Products Company Limited Building 7, No. 1510 Chuanqiao Road China (Shanghai) Pilot Free Trade Zone 201206 Shanghai China	**Manufacture**
Trophy 4 rue F. Pelloutier Croissy-Beaubourg 77435 Marne-la-Vallée Cedex 2 France	**Design** **Development** **Manufacture**

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