

EU Quality Management System Certificate

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

MDR 753349 R000

Manufacturer: Dentsply LLC

Address:

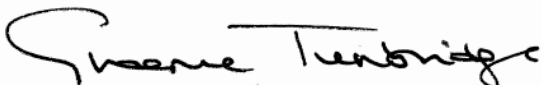
1301 Smile Way
York
Pennsylvania
17404
USA

Single Registration Number: US-MF-000022592

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 devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional 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: **2023-03-16**

Current Issue Date: **2024-03-25**

Starting Validity Date: **2024-03-25**

Expiry Date: **2028-03-15**

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EU Authorised Representative: DeguDent GmbH

Address:

Rodenbacher Chaussee 4
63457 Hanau-Wolfgang
Germany

EU Authorised Representative: Dentsply DeTrey GmbH

Address:

De-Trey-Strasse 1
Konstanz
D-78467
Germany



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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Dental active devices and accessories	Class IIa
Denture base and teeth for prosthetic dentistry	Class IIa
Dental crown and bridge for prosthetic dentistry	Class IIa implantable



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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.

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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
2023-03-16	3484134	Issued
2023-11-27	30009286	Amended --- Change of manufacturer name to Dentsply LLC. Addition and Removal of subcontractors for active, denture base and teeth devices. Addition of authorised representative to DeguDent GmbH Rodenbacher Chaussee 4 63457 Hanau-Wolfgang Germany Supplemented --- Addition of device group Denture base and teeth for prosthetic dentistry.
Current	30112611	Amended --- Addition of subcontractor for dental crown and bridge for prosthetic dentistry. Supplemented --- Addition of device group dental crown and bridge for prosthetic dentistry.

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