



Document Detail

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Title: Calibra Ceram Adhesive Resin Cement DOC
Comment:
Status: CURRENT
Effective Date: 05-Sep-2023

Approval

<u>Owner Role</u>	<u>Sign-off By</u>	<u>Sign-off Date</u>	
0070-Document Control Milford Document Control	Michelle Wilson	31-Aug-2023 5:57 pm	GMT
0070-RA Approver Milford Regulatory Affairs Approver	Stacia Preston	05-Sep-2023 1:48 pm	GMT

CALIBRA® CERAM ADHESIVE RESIN CEMENT
DoC - DECLARATION OF CONFORMITY



CONSUMABLE GROUP QUALITY SYSTEM – MULTI-USE FORM

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Manufacturer:	Dentsply LLC, also trading as DENTSPLY Caulk 38 West Clarke Avenue, Milford DE 19963 USA Single Registration Number (SRN): US-MF-000016555
Authorized EU-representative:	Dentsply DeTrey GmbH, De-Trey-Strasse 1, 78467 Konstanz, Germany Single Registration Number (SRN): DE-AR-000005904
Authorized UK-representative:	N/A
PRODUCT CODE / CATALOGUE NUMBER	NAME
607101	Calibra® Ceram Adhesive Resin Cement – Sample
607101B	Calibra® Ceram Adhesive Resin Cement – Sample
607101K	Calibra® Ceram Adhesive Resin Cement – Sample
607191	Calibra® Ceram Adhesive Resin Cement Syringe Refill – Shade Light
607191B	Calibra® Ceram Adhesive Resin Cement Syringe Refill – Shade Light
607191K	Calibra® Ceram Adhesive Resin Cement Syringe Refill – Shade Light
607192	Calibra® Ceram Adhesive Resin Cement Syringe Refill – Shade Medium
607192B	Calibra® Ceram Adhesive Resin Cement Syringe Refill – Shade Medium
607192K	Calibra® Ceram Adhesive Resin Cement Syringe Refill – Shade Medium
607194	Calibra® Ceram Adhesive Resin Cement Syringe Refill – Shade Translucent
607194B	Calibra® Ceram Adhesive Resin Cement Syringe Refill – Shade Translucent
607194K	Calibra® Ceram Adhesive Resin Cement Syringe Refill – Shade Translucent
607195	Calibra® Ceram Adhesive Resin Cement Syringe Refill – Shade Opaque
607195B	Calibra® Ceram Adhesive Resin Cement Syringe Refill – Shade Opaque
607195K	Calibra® Ceram Adhesive Resin Cement Syringe Refill – Shade Opaque
607196	Calibra® Ceram Adhesive Resin Cement Syringe Refill – Shade Bleach
607196B	Calibra® Ceram Adhesive Resin Cement Syringe Refill – Shade Bleach
607196K	Calibra® Ceram Adhesive Resin Cement Syringe Refill – Shade Bleach
60667380	Calibra® Ceram Adhesive Resin Cement – Combo Kit P&B Active
60667382	Calibra® Ceram Adhesive Resin Cement – Combo Kit P&B Universal
Classification and Rules (EU and UK)	EU class: Class IIa following Rule 8, long term, invasive, implantable device ACCORDING TO ANNEX IX Section III
Basic UDI-DI	++D002DENTALCEMENTSC6
EMDN code / description	Q01010102 Temporary and Permanent Dental Restoration Cements
GMDN code / description	35870 Dental Composite Resin
Intended purpose	Calibra® Ceram Adhesive Resin Cement is designed to be used following the application of a compatible dentin/enamel adhesive.
<p>WE HEREWITH DECLARE THAT THE ABOVE-MENTIONED PRODUCTS MEET THE PROVISIONS OF</p> <p>- THE COUNCIL DIRECTIVE 93/42/EEC AMENDED BY 2007/47/EC FOR MEDICAL DEVICES, IN ACCORDANCE WITH ANNEX I</p> <p>ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER. THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.</p>	
External references (Common Specifications, Standards, Regulations) applied	TF034-CL
EC Certificate:	EC certificate number: CE668748 Notified Body name: BSI Group the Netherlands Notified Body address: Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands Notified Body ID: 2797
UK Certificate	N/A

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Reference to the corresponding Technical Documentation	TF034
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Dentsply LLC, also trading as
DENTSPLY Caulk
38 West Clarke Avenue
Milford DE 19963
USA

8/31/23

Stacia Preston
Regulatory Affairs Manager

Date

FORM NO	8000-FM-008-05	REVISION LEVEL	6
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