



Document Detail

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Title: Calibra Ceram Adhesive Resin Cement DOC
Comment:
Status: CURRENT
Effective Date: 25-Mar-2025

Approval

<u>Owner Role</u>	<u>Sign-off By</u>	<u>Sign-off Date</u>	
0070-Document Control Milford Document Control	Michelle Wilson	24-Mar-2025 5:46 pm	GMT
0070-RA Approver Milford Regulatory Affairs Approver	Stacia Preston	25-Mar-2025 12:23 pm	GMT

**CALIBRA® CERAM ADHESIVE RESIN CEMENT
DoC - DECLARATION OF CONFORMITY**



CONSUMABLE GROUP QUALITY SYSTEM – MULTI-USE FORM

RECORD NUMBER	MILFORD 0070-TF034-DOC-5	REVISION LEVEL	16	PAGE NO	Page 1 of 2
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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
Classification and Rules (EU and UK)	EU class: Class IIa Rule 19 – device incorporates or consists of nanomaterial with negligible potential for internal exposure ACCORDING TO ANNEX VIII OF THE REGULATION 2017/745 UK Class: N/A ACCORDING TO ANNEX IX OF THE DIRECTIVE 93/42/EC AND UK MDR 2002
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> <ul style="list-style-type: none"> - THE REGULATIONS EU/2017/745 ON MEDICAL DEVICES, IN ACCORDANCE WITH THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEX IX ANNEXES IX CHAPTER I and III. - THE MEDICAL DEVICE REGULATIONS 2002 (SI 618) as subsequently amended by the EU EXIT REGULATIONS OF 2019 (SI 791) and 2020 (SI 1478). <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-LAER
EC Certificate:	MDR 744246 BSI Group the Netherlands

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RECORD NUMBER	MILFORD 0070-TF034-DOC-5	REVISION LEVEL	16	PAGE NO	Page 2 of 2
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	Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands Notified Body identification number 2797 Certificate Expiration Date: August 26, 2029
UK Certificate	N/A
Reference to the corresponding Technical Documentation	Technical Documentation name: TF034 Calibra Family and SmartCem2 Technical Documentation Index: TF034-TDI

Dentsply LLC, also trading as
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Stacia Preston

3/24/25

Stacia Preston
Regulatory Compliance Manager

Date