



Document Detail

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Title: Calibra Universal+ Versatile Resin Cement Declaration of Conformity
Comment:
Status: CURRENT
Effective Date: 07-Apr-2025

Approval

<u>Owner Role</u>	<u>Sign-off By</u>	<u>Sign-off Date</u>	
0070-Document Control Milford Document Control	Michelle Wilson	02-Apr-2025 3:00 pm	GMT
0070-RA Approver Milford Regulatory Affairs Approver	Stacia Preston	07-Apr-2025 6:16 pm	GMT

**CALIBRA® UNIVERSAL+ VERSATILE 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
607400NA	Calibra® Universal+ Versatile Resin Cement Syringe Introductory Kit
607402NA	Calibra® Universal+ Versatile Resin Cement Syringe Refill – Light Shade
607403NA	Calibra® Universal+ Versatile Resin Cement Syringe Refill – Medium Shade
607405NA	Calibra® Universal+ Versatile Resin Cement Syringe Refill – Translucent Shade
607406NA	Calibra® Universal+ Versatile Resin Cement Syringe Refill – Opaque Shade
607407NA	Calibra® Universal+ Versatile Resin Cement Syringe Refill – Bleach Shade
Classification and Rules (EU and UK)	EU class: Class IIa following Rule 19 - device incorporates or consists of nanomaterial with negligible potential for internal exposure and Rule 8 – long term, implantable, invasive device 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® Universal+ Versatile Resin Cement is a two-component, visible light-cured, dual-cured or self-cured high strength resin cement which contains fluoride. Calibra® Universal+ Cement combines esthetic shading with a self-etching adhesive, making it suitable for the permanent cementation of metal, PFM, ceramic and porcelain inlays, onlays, crowns and bridges and endodontic posts without application of a separate dentin/enamel adhesive bonding agent/system. For cementing resin composite, lower strength porcelain/ceramic or minimally retentive restorations, Calibra® Universal+ Cement should 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 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 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: Calibra family and SmartCem2 Technical Documentation Index: TF034-TDI

CALIBRA® UNIVERSAL+ VERSATILE RESIN CEMENT				 Dentsply Sirona	
DoC - DECLARATION OF CONFORMITY					
CONSUMABLE GROUP QUALITY SYSTEM – MULTI-USE FORM					
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Dentsply LLC, also trading as
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38 West Clarke Avenue
Milford DE 19963
USA



Stacia Preston
Regulatory Compliance Manager

4/1/25

Date

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