




Document Detail

Type: 0070-Tech File DOC
Document No.: 0070-TF002-DOC-1[16]
Title: Dycal Calcium Hydroxide Composition - Declaration of Conformity
Comment:
Status: CURRENT
Effective Date: 06-Oct-2022


Approval

<u>Owner Role</u>	<u>Sign-off By</u>	<u>Sign-off Date</u>	
0070-Document Control Milford Document Control	Michelle Wilson	04-Oct-2022 3:47 pm	GMT
0070-RA Approver Milford Regulatory Affairs Approver	Stacia Preston	06-Oct-2022 5:17 pm	GMT


DYCAL®					
RADIOPAQUE CALCIUM HYDROXIDE COMPOSITION DoC - DECLARATION OF CONFORMITY					
CONSUMABLE GROUP QUALITY SYSTEM – MULTI-USE FORM					
RECORD NUMBER	MILFORD 0070-TF002-DOC-1	REVISION LEVEL	16	PAGE NO	Page 1 of 2

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
623400	Dycal® Radiopaque Calcium Hydroxide Composition Ivory Complete Kit
623401Y	Dycal® Radiopaque Calcium Hydroxide Composition Ivory
623450	Dycal® Radiopaque Calcium Hydroxide Composition Dentin Complete Kit
623451Y	Dycal® Radiopaque Calcium Hydroxide Composition Dentin
623701	Dycal® Radiopaque Calcium Hydroxide Composition Ivory Six Pack
623702	Dycal® Radiopaque Calcium Hydroxide Composition Dentin Six Pack
623801	Dycal® Radiopaque Calcium Hydroxide Composition Ivory Standard Package
623802	Dycal® Radiopaque Calcium Hydroxide Composition Dentin Standard Package
611.05.501	Dycal® in Tubes, Standard Pack Shade Ivory
611.05.606	Dycal® in Tubes, ECO (6-Packs) Shade Ivory
611.06.501	Dycal® in Tubes, Standard Pack Shade Dentin
611.06.606	Dycal® in Tubes, ECO (6-Packs) Shade Dentin
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	++D002BASE55
Intended purpose: Dycal® Radiopaque Calcium Hydroxide Composition is designed for use in direct and indirect pulp capping and as a protective liner under dental adhesives, varnishes, filling materials, cements, and other base materials. It will not inhibit the polymerization of acrylic and composite restorations.	
WE HEREWITH DECLARE THAT THE ABOVE-MENTIONED PRODUCTS MEET THE PROVISIONS OF - THE COUNCIL DIRECTIVE 93/42/EEC AMENDED BY 2007/47/EC FOR MEDICAL DEVICES, IN ACCORDANCE WITH ANNEX I ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER. THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.	
Common Specifications applied:	N/A
Technical standards ref.:	N/A
EC Certificate:	CE668748 BSI Group the Netherlands Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands Notified Body identification number 2797
UK Certificate	N/A
Reference to the corresponding Technical Documentation	TF002
Expiration date for the DoC –	N/A

FORM NO	8000-FM-008-05	REVISION LEVEL	4
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DYCAL® RADIOPAQUE CALCIUM HYDROXIDE COMPOSITION DoC - DECLARATION OF CONFORMITY					
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Dentsply LLC, also trading as
DENTSPLY Caulk
38 West Clarke Avenue
Milford DE 19963
USA


10/4/22

Stacia Preston Date
Regulatory Affairs Manager

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