



Document Detail

Type: 0070-Tech File DOC
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Title: SDR Flow + Bulk Fill Flowable DOC
Comment:
Status: CURRENT
Effective Date: 22-Apr-2024

Approval

<u>Owner Role</u>	<u>Sign-off By</u>	<u>Sign-off Date</u>	
0070-Document Control Milford Document Control	Michelle Wilson	17-Apr-2024 6:43 pm	GMT
0070-RA Approver Milford Regulatory Affairs Approver	Stacia Preston	22-Apr-2024 11:58 am	GMT

SDR® FLOW+ BULK FILL FLOWABLE
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
61c130G	SDR® flow+ Bulk Fill Flowable Syringe Refill Universal Shade
606.03.031	SDR® flow+ Bulk Fill Flowable 4 Compula Sample
606.03.032	SDR® flow+ Bulk Fill Flowable Intro Kit with Prime & Bond active
606.03.033	SDR® flow+ Bulk Fill Flowable Compula ECO Refill Universal Shade
606.03.034	SDR® flow+ Bulk Fill Flowable Collector's Edition
606.03.039	SDR® flow+ Bulk Fill Flowable Sample All Shades
606.03.040	SDR® flow+ Bulk Fill Flowable Compula Refill Universal Shade
606.03.041	SDR® flow+ Bulk Fill Flowable Compula Refill Universal A1 Shade
606.03.042	SDR® flow+ Bulk Fill Flowable Compula Refill Universal A2 Shade
606.03.043	SDR® flow+ Bulk Fill Flowable Compula Refill Universal A3 Shade
606.03.050	SDR® flow+ Bulk Fill Flowable Syringe ECO Refill Universal Shade
Classification and Rules (EU and UK)	EU class: Class IIa following Rule 8, long term, implantable, invasive device ACCORDING TO ANNEX IX Section III
Basic UDI-DI	++D002DENTALCOMPOSITES68
EMDN code / description	Q01010103 Dental Conservation Composites
GMDN code / description	35870 Dental composite resin
Intended purpose	SDR® flow+ Bulk Fill Flowable is a one-component, fluoride-containing, visible light cured, radiopaque resin composite restorative material. It is designed to be used as a base in Class I and II restorations. It is also suitable as a stand-alone restorative material in non-occlusal-contact applications.
<p>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.</p>	
External references (Common Specifications, Standards, Regulations) applied	TF038-LAER
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	TF038

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Dentsply LLC, also trading as
DENTSPLY Caulk
38 West Clarke Avenue
Milford DE 19963
USA

4/16/24

Stacia Preston
Regulatory Compliance Manager

Date

FORM NO	8000-FM-008-05	REVISION LEVEL	4
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