Document Detail

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Title: SDR Plus Bulk Fill Flowable Declaration of Conformity

Comment:

Status: CURRENT

Effective Date: 22-Apr-2024

Approval

Owner Role	Sign-off By	Sign-off Date	
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

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**
61C101P	SDR® Plus Bulk Fill Flowable Compula® Tips Refill – Shade Universal
61C103P	SDR® Plus Bulk Fill Flowable Compula® Tips Bulk Refill – Shade Universal
61C104P	SDR® Plus Bulk Fill Flowable Syringe Sampler
61C106P	SDR® Plus Bulk Fill Flowable Compula® Tips Refill – Shade A1
61C107P	SDR® Plus Bulk Fill Flowable Compula® Tips Refill – Shade A2
61C108P	SDR® Plus Bulk Fill Flowable Compula® Tips Refill – Shade A3
61C130P	SDR® Plus Bulk Fill Flowable Syringe Refill – Shade Universal
606.03.044	SDR® Plus Bulk Fill Flowable 4 Compula Sample
606.03.045	SDR® Plus Bulk Fill Flowable Syringe ECO Refill
606.03.047	SDR® Plus Bulk Fill Flowable Intro Kit with Prime & Bond Universal
606.03.048	SDR® Plus Bulk Fill Flowable Collector's Edition Kit
606.03.049	SDR® Plus Bulk Fill Flowable Sample (all Shades)
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® Plus 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.
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.	
External references (Common Specifications, Standards, Regulations) applied	TF038-LAER
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

Dentsply LLC, also trading as
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SPreston 4/16/24

Stacia Preston
Regulatory Compliance Manager

Date