THE DENTAL SOLUTIONS COMPANY™

Dentsply Sirona

SDR® Plus Bulk Fill Flowable

EC Declaration of Conformity

Manufacturer's Name Address:	DENTSPLY Sirona 38 West Clarke Avenue Milford DE 19963 USA
Authorized EC Representative Name and Address:	DENTSPLY DeTrey GmbH DeTrey Strasse 1 Konstanz Germany D-78467
Unique Product Identification:	61C101P SDR® Plus Compula Refill Universal 61C103P SDR® Plus Compula ECO Refill Universal 61C106P SDR® Plus Compula Refill A1 61C107P SDR® Plus Compula Refill A2 61C108P SDR® Plus Compula Refill A3 61C111P SDR® Plus Compula Syringe Tip Refill 61C130P SDR® Plus Syringe Refill 606.03.044 SDR® Plus 4 Compula Sample 606.03.045 SDR® Plus Syringe ECO Refill 606.03.046 SDR® Plus 10 Compula Sample 606.03.047 SDR® Plus Intro Kit with Prime&Bond universal 606.03.048 SDR® Plus Collector's Edition Kit
Description:	SDR Plus Bulk Fill Flowable Base 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. SDR Plus material has handling characteristics typical of a "flowable" composite, but can be placed in 4mm increments with minimal polymerization stress. SDR Plus material has a self-leveling feature that allows intimate adaptation to the prepared cavity walls. When used as a base/liner, it is designed to be overlayed with a methacrylate based universal/posterior composite for replacing missing occlusal/facial enamel.
GMDN Code:	38764 – Light-cured dental restorative composite resin
Product Classification Per Annex IX:	This product is classified as a Class IIa Medical Device under Annex IX Section III, rule 8, implantable device, long term.

EC Declaration of Conformity:

The above listed medical device(s) conform to the requirements of Council Directive 93/42/EEC *as amended by Council Directive 2007/47/EC* and meet the relevant Essential Requirements of Annex I. All devices are designed, manufactured, tested, and released for sale in accordance with the technical documentation.

This declaration is made on the basis of the Certificate of Conformity US97/10442 issued by SGS United Kingdom Ltd. Systems & Services Certification with Notified Body identification number 0120 in accordance with Annex II (excluding Section 4) of the Directive.

DENTSPLY Sirona maintains a quality management system that complies with the United States Food and Drug Administration 21 CFR Part 820 & 211, ISO 13485:2003, CMDR, PMDL (MO 169) and the European Union Council Directive 93/42/EEC.

Authorized Signature:

Name: Karen Trovalli
QA/RA Manager

Date of Issuance: August 3, 2017