3M ESPE
Dental Products

2510 Conway Avenue
St. Paul, MN 55144 USA

EC DECLARATION OF CONFORMITY

93/42/EEC on Medical Devices (MDD) Annex II excluding (4).

Manufacturer:
3M ESPE Dental Products
2510 Conway Avenue
St. Paul, Minnesota 55144-1000
USA

EC Certificate No: G1 16 05 45735 030
Valid until: 2021-12-03

GMDN CODE: 35870; Dental composite resin

Manufacturing Facility:
3M ESPE Dental Products
2111 McGaw Avenue
Irvine, California 92614
USA

Product Family: Resin-Based Restorative Materials

Product: Filtek™ Supreme Flowable Restorative syringes

EC Product Class: IIa
Rule: 8
Per Annex IX of the Medical Device Directive

Declaration of Conformity

3M ESPE Dental Products has sole responsibility and declares that the devices listed on the attached Device Schedule conform to the relevant provisions of the EC Council Directive 93/42/EEC dated 14 June 1993 and are in accordance with ISO 13485:2016, Medical devices - Quality management systems – Requirements for regulatory purposes, as implemented by the European Union's Medical Devices Regulations and verified by TüV SüD Product Service GMBH, Ridlerstrasse 65, 80339 Munich Germany, CE 0123.

3M ESPE Dental Products has appointed 3M Deutschland GmbH as our EU Authorized Representative.

3M Deutschland GmbH
Carl-Schurz-Strasse 1
41453 Neuss, Germany

Suzanne Leung	Manager 3M ESPE Regulatory Affairs	St.Paul, MN USA	18 Feb 2020
Suzanne Leung	Title	Location	Date

EC DECLARATION OF CONFORMITY

Product Family: Resin-Based Restorative Materials
Device Description: Non-Sterile Dental Restorative Material
EC Product Class (Per Annex IX Rules): Class: IIa Rule:8
Product:
- Filtek™ Supreme Flowable Restorative

Item	Catalogue/Order Number
Syringe Refills	
Filtek Supreme Flowable Restorative 2-2g A1 Shade Syringe 20 dispensing tips Instructions for Use	3930A1
Filtek Supreme Flowable Restorative 2-2g A2 Shade Syringe 20 dispensing tips Instructions for Use	3930A2
Filtek Supreme Flowable Restorative 2-2g A3 Shade Syringe 20 dispensing tips Instructions for Use	3930A3
Filtek Supreme Flowable Restorative 2-2g A3.5 Shade Syringe 20 dispensing tips Instructions for Use	3930A3.5
Filtek Supreme Flowable Restorative 2-2g A4 Shade Syringe 20 dispensing tips Instructions for Use	3930A4
Filtek Supreme Flowable Restorative 2-2g B1 Shade Syringe 20 dispensing tips Instructions for Use	3930B1
Filtek Supreme Flowable Restorative 2-2g B2 Shade Syringe 20 dispensing tips Instructions for Use	3930B2
Filtek Supreme Flowable Restorative 2-2g C2 Shade Syringe 20 dispensing tips Instructions for Use	3930C2
Filtek Supreme Flowable Restorative 2-2g D2 Shade Syringe 20 dispensing tips Instructions for Use	3930D2
Filtek Supreme Flowable Restorative 2-2g W Shade Syringe 20 dispensing tips Instructions for Use	3930W
Filtek Supreme Flowable Restorative 2-2g XW Shade Syringe 20 dispensing tips Instructions for Use	3930XW

Filtek Supreme Flowable Restorative 2-2g OA3 Shade Syringe 20 dispensing tips Instructions for Use	3930OA3
Samples	
Filtek Supreme Flowable Restorative 1-1g syringe A2 shade 20 dispensing tips Instructions for Use	3930A2-S Not for Sale
Filtek Supreme Flowable Restorative 1-1g syringe A3 shade 20 dispensing tips Instructions for Use	3930A3-S Not for Sale