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

UMDNS CODE: 17-619

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

Product Family: Resin Based Restorative Materials

Product: Filtek™ Bulk Fill Flowable Restorative

CE Mark Date: Jan. 27, 2012

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 13485:2003, 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

Gretchen E. Keenan	Manager 3M ESPE Regulatory Affairs	St.Paul, MN USA	2 May 2017
	Title	Location	Date

Revision 17Nov2016

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™ Bulk Fill Flowable Restorative

Item	Catalogue/Order Number
Syringe Refills	
Filtek Bulk Fill Flowable Restorative • 2 x 2g Universal Shade Syringe • 20 dispensing tips • Technique guide • Instructions for Use	4862U
Filtek Bulk Fill Flowable Restorative • 2 x 2g A1 Shade Syringe • 20 dispensing tips • Technique guide • Instructions for Use	4862A1
Filtek Bulk Fill Flowable Restorative • 2 x 2g A2 Shade Syringe • 20 dispensing tips • Technique guide • Instructions for Use	4862A2
Filtek Bulk Fill Flowable Restorative • 2 x 2g A3 Shade Syringe • 20 dispensing tips • Technique guide • Instructions for Use	4862A3
Capsule Refills	
Filtek Bulk Fill Flowable Restorative • 15 - 0.2g Universal Shade Capsules • Technique guide • Instructions for Use	4861U
Filtek Bulk Fill Flowable Restorative • 15 - 0.2g A1 Shade Capsules • Technique guide • Instructions for Use	4861A1
Filtek Bulk Fill Flowable Restorative • 15 - 0.2g A2 Shade Capsules • Technique guide • Instructions for Use	4861A2
Filtek Bulk Fill Flowable Restorative • 15 - 0.2g A3 Shade Capsules • Technique guide • Instructions for Use	4861A3
Samples	

Filtek Bulk Fill Flowable Restorative • 1 x 1g Universal Shade Syringe • 20 dispensing tips • Instructions for Use	4862U-S Not for Sale
Filtek Bulk Fill Flowable Restorative • 5 - 0.2g Universal Shade Capsules • Instructions for Use	4861U-S Not for Sale
Accessories	
Filtek Bulk Fill Flowable Dispensing Tips • 20 – Dispensing Tips	3740T
Restorative Dispenser*	5707SD