3M ESPE
Dental Products

2510 Conway Avenue
St. Paul, MN 55144 USA

EC DECLARATION OF CONFORMITY

93/42/EEC on Medical Devices (MDD) as amended by 2007/47/EC

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

EC Certificate

Certificate No:	G1 045735 0039
Valid until:	2024-05-26
Conformity Route:	Full Quality Assurance System Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)

Product Family:	IIa	Product(s):	Filtek™ P60 Posterior Restorative
Device Class:	IIa per Rule VIII in Annex IX of 93/42/EEC as amended by 2007/47/EC		

Declaration of Conformity

3M ESPE Dental Products has sole responsibility and declares that the CE marked device(s) in this declaration fulfills the relevant provisions of EC Council Directive 93/42/EEC, as amended by 2007/47/EC, on the approximation of the laws of the European Union Member States concerning medical devices and are in accordance with EN ISO 13485:2016, Medical devices - Quality management systems – Requirements for regulatory purpose.

This declaration is made on the basis of the Full Quality Assurance System EC certificate above which has been delivered 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

Suzanne Leung, PhD., RAC
Regulatory Affairs Director
3M ESPE Dental Products

08 July 2021

Date

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Item Number	Description
Kit – Eastern Europe	
4720E	Filtek P60 Posterior Restorative System • 3 - 4 g Syringes, 1 each of 3 different shades • 1 - 3 g Bottle Adper™ Single Bond 2 Adhesive • 1 - 3 ml Syringe Scotchbond™ Universal Etchant • 25 - Dispensing tips • 1 - Shade guide • 2 - Brush handles • 25 - Fiber tips • Mix Wells • Mix Pad • Technique guide • Instructions for Use
Kit – Western Europe	
4720	Filtek P60 Posterior Restorative System • 3 - 4 g Syringes, 1 each of 3 different shades • 1 - 3 g Bottle Adper™ Scotchbond™ 1 XT Adhesive • 1 - 3 ml Syringe Scotchbond™ Universal Etchant • 25 - Dispensing tips • 1 - Shade guide • 2 - Brush handles • 25 - Fiber tips • Mix Wells • Mix Pad • Technique guide • Instructions for Use
Refills – Eastern and Western Europe	
4720A3	Filtek P60 Posterior Restorative A3 Shade • 1 each - 4 g syringe • Instructions for Use
4720B2	Filtek P60 Posterior Restorative B2 Shade • 1 each - 4 g syringe • Instructions for Use
4720C2	Filtek P60 Posterior Restorative C2 Shade • 1 each - 4 g syringe • Instructions for Use
Kit – Middle East	
8100L	Filtek™ P60 Posterior Restorative System • 3 - 4 g Syringes, 1 each of 3 different shades • 1 - 3 g Bottle Adper™ Single Bond 2 Adhesive • 1 - 3 ml Syringe Scotchbond™ Universal Etchant • 25 - Dispensing tips • 1 - Shade Guide • 2 - Brush handles • 25 - Fiber Tips • Mix Wells • Mix Pad • Technique Guide • Instructions for Use
Refill – Middle East	
8100A3	Filtek P60 Posterior Restorative A3 Shade • 1 each - 4 g syringe • Instructions for Use

8100B2	Filtek P60 Posterior Restorative B2 Shade • 1 each - 4 g syringe • Instructions for Use
8100C2	Filtek P60 Posterior Restorative C2 Shade • 1 each - 4 g syringe • Instructions for Use