



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

Manufacturing Facility:

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

Product Family: Resin-Based Restorative
Materials

Product: Filtek™ P60 Posterior
Restorative

EC Product Class: IIa
Rule: 8

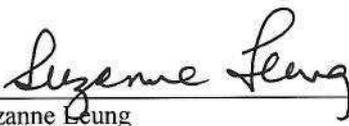
Per Annex IX of the Medical Device Directive

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
Title

St. Paul, MN USA
Location

09 Sep 2019
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™ P60 Posterior Restorative

Item Number	Description
	Kits
	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
	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

	<ul style="list-style-type: none"> ◆ 2 - Brush handles ◆ 25 - Fiber Tips ◆ Mix Wells ◆ Mix Pad ◆ Technique Guide ◆ Instructions for Use
	Refills Middle East
8100A3	Filtek P60 Posterior Restorative A3 Shade <ul style="list-style-type: none"> ◆ 1 each - 4 g syringe ◆ Instructions for Use
8100B2	Filtek P60 Posterior Restorative B2 Shade <ul style="list-style-type: none"> ◆ 1 each - 4 g syringe ◆ Instructions for Use
8100C2	Filtek P60 Posterior Restorative C2 Shade <ul style="list-style-type: none"> ◆ 1 each - 4 g syringe ◆ Instructions for Use