



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

Manufacturing Facility:

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

Product Family: Resin-Based Restorative
Materials

Product: 3M™ Filtek™ One Bulk Fill
Restorative

EC Product Class: IIa
Rule: 8

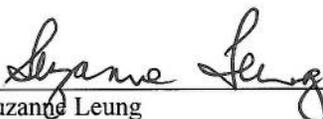
Per Annex IX of the Medical Device Directive

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

06 Sep 2019
Date

EC DECLARATION OF CONFORMITY

Product Family:

Device Description:

EC Product Class (Per Annex IX Rules):

Product:

Resin-Based Restorative Materials

Non-Sterile Dental Restorative Material

Class: IIa Rule: 8

◆ 3M™ Filtek™ One Bulk Fill Restorative

NA/WE/ANZ/SA

Item	Catalogue/Order Number
Syringe Refills	
Filtek One Bulk Fill Restorative <ul style="list-style-type: none"> • 1- 4g A1 Shade Syringe • Instructions for Use 	4866A1
Filtek One Bulk Fill Restorative <ul style="list-style-type: none"> • 1- 4g A2 Shade Syringe • Instructions for Use 	4866A2
Filtek One Bulk Fill Restorative <ul style="list-style-type: none"> • 1- 4g A3 Shade Syringe • Instructions for Use 	4866A3
Filtek One Bulk Fill Restorative <ul style="list-style-type: none"> • 1- 4g A3.5 Shade Syringe • Instructions for Use 	4866A3.5
Filtek One Bulk Fill Restorative <ul style="list-style-type: none"> • 1- 4g B1 Shade Syringe • Instructions for Use 	4866B1
Filtek One Bulk Fill Restorative <ul style="list-style-type: none"> • 1- 4g C2 Shade Syringe • Instructions for Use 	4866C2
Filtek One Bulk Fill Restorative <ul style="list-style-type: none"> • 1- 4g W Shade Syringe • Instructions for Use 	4866W
Capsule Refills	
Filtek One Bulk Fill Restorative <ul style="list-style-type: none"> • 20 - 0.2g A1 Shade Capsules • Instructions for Use 	4867A1
Filtek One Bulk Fill Restorative <ul style="list-style-type: none"> • 20 - 0.2g A2 Shade Capsules • Instructions for Use 	4867A2
Filtek One Bulk Fill Restorative <ul style="list-style-type: none"> • 20 - 0.2g A3 Shade Capsules • Instructions for Use 	4867A3
Filtek One Bulk Fill Restorative <ul style="list-style-type: none"> • 20 - 0.2g A3.5 Shade Capsules • Instructions for Use 	4867A3.5
Filtek One Bulk Fill Restorative <ul style="list-style-type: none"> • 20 - 0.2g B1 Shade Capsules • Instructions for Use 	4867B1
Filtek One Bulk Fill Restorative <ul style="list-style-type: none"> • 20 - 0.2g C2 Shade Capsules • Instructions for Use 	4867C2
Filtek One Bulk Fill Restorative <ul style="list-style-type: none"> • 20 - 0.2g W Shade Capsules • Instructions for Use 	4867W
Samples	

Filtek One Bulk Fill Restorative <ul style="list-style-type: none"> • 1 – 1g A2 Shade Syringe • Instructions for Use 	4866A2-S
Filtek One Bulk Fill Restorative <ul style="list-style-type: none"> • 5 – 0.2g A2 Shade Capsules • Instructions for Use 	4867A2-S
Filtek One Bulk Fill Restorative <ul style="list-style-type: none"> • 5 – 0.2g A3 Shade Capsule Instructions for Use	4867A3-S
Efficient Restorative Procedure Solutions Pack <ul style="list-style-type: none"> • 1 - 1g Filtek One Bulk Fill Restorative A2 Shade Syringe • 5 – Scotchbond™ Universal Adhesive Unit Dose Applicators • Sof-Lex™ Diamond Polishing System <ul style="list-style-type: none"> 3 – Pre-polishing Spirals 3 – Diamond Polishing Spirals • 1 – Mandrel (RA) • Instructions for Use 	4866-SP
Efficient Restorative Procedure Solutions Pack <ul style="list-style-type: none"> • 5 – 0.2g Filtek One Bulk Fill Restorative A2 Shade Capsules • 5 – Scotchbond™ Universal Adhesive Unit Dose Applicators • Sof-Lex™ Diamond Polishing System <ul style="list-style-type: none"> 3 – Pre-polishing Spirals 3 – Diamond Polishing Spirals • 1 – Mandrel (RA) • Instructions for Use 	4867-CP

CEE/MEA/RUS

Item	Catalogue/Order Number
Syringe Refills	
Filtek One Bulk Fill Restorative <ul style="list-style-type: none"> • 1- 4g A1 Shade Syringe • Instructions for Use 	4870A1
Filtek One Bulk Fill Restorative <ul style="list-style-type: none"> • 1- 4g A2 Shade Syringe • Instructions for Use 	4870A2
Filtek One Bulk Fill Restorative <ul style="list-style-type: none"> • 1- 4g A3 Shade Syringe • Instructions for Use 	4870A3
Filtek One Bulk Fill Restorative <ul style="list-style-type: none"> • 1- 4g A3.5 Shade Syringe • Instructions for Use 	4870A3.5
Filtek One Bulk Fill Restorative <ul style="list-style-type: none"> • 1- 4g B1 Shade Syringe • Instructions for Use 	4870B1
Filtek One Bulk Fill Restorative <ul style="list-style-type: none"> • 1- 4g C2 Shade Syringe • Instructions for Use 	4870C2
Filtek One Bulk Fill Restorative <ul style="list-style-type: none"> • 1- 4g W Shade Syringe • Instructions for Use 	4870W
Capsule Refills	
Filtek One Bulk Fill Restorative <ul style="list-style-type: none"> • 20 - 0.2g A1 Shade Capsules • Instructions for Use 	4871A1

Filtek One Bulk Fill Restorative <ul style="list-style-type: none"> • 20 - 0.2g A2 Shade Capsules • Instructions for Use 	4871A2
Filtek One Bulk Fill Restorative <ul style="list-style-type: none"> • 20 - 0.2g A3 Shade Capsules • Instructions for Use 	4871A3
Filtek One Bulk Fill Restorative <ul style="list-style-type: none"> • 20 - 0.2g A3.5 Shade Capsules • Instructions for Use 	4871A3.5
Filtek One Bulk Fill Restorative <ul style="list-style-type: none"> • 20 - 0.2g B1 Shade Capsules • Instructions for Use 	4871B1
Filtek One Bulk Fill Restorative <ul style="list-style-type: none"> • 20 - 0.2g C2 Shade Capsules • Instructions for Use 	4871C2
Filtek One Bulk Fill Restorative <ul style="list-style-type: none"> • 20 - 0.2g W Shade Capsules • Instructions for Use 	4871W
Samples	
Filtek One Bulk Fill Restorative <ul style="list-style-type: none"> • 1 – 1g A2 Shade Syringe • Instructions for Use 	4870A2-S
Filtek One Bulk Fill Restorative <ul style="list-style-type: none"> • 5 – 0.2g A2 Shade Capsules • Instructions for Use 	4871A2-S
Efficient Restorative Procedure Solutions Pack <ul style="list-style-type: none"> • 1 - 1g Filtek One Bulk Fill Restorative A2 Shade Syringe • 5 – Scotchbond™ Universal Adhesive Unit Dose Applicators • Sof-Lex™ Diamond Polishing System 3 – Pre-polishing Spirals 3 – Diamond Polishing Spirals 1 – Mandrel (RA) <ul style="list-style-type: none"> • Instructions for Use 	4870-SP
Efficient Restorative Procedure Solutions Pack <ul style="list-style-type: none"> • 5 – 0.2g Filtek One Bulk Fill Restorative A2 Shade Capsules • 5 – Scotchbond™ Universal Adhesive Unit Dose Applicators • Sof-Lex™ Diamond Polishing System 3 – Pre-polishing Spirals 3 – Diamond Polishing Spirals 1 – Mandrel (RA) <ul style="list-style-type: none"> • Instructions for Use 	4871-CP