



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: Resin-Based Restorative
Materials

Product(s): 3M™ Filtek™ One Bulk Fill
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, PhD., RAC
Regulatory Affairs Director
3M ESPE Dental Products

Date

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Item Number	Description
NA/WE/ANZ/SA	
Syringe Refills	
4866A1	Filtek One Bulk Fill Restorative 1- 4g A1 Shade Syringe - Instructions for Use
4866A2	Filtek One Bulk Fill Restorative 1- 4g A2 Shade Syringe - Instructions for Use
4866A3	Filtek One Bulk Fill Restorative 1- 4g A3 Shade Syringe - Instructions for Use
4866A3.5	Filtek One Bulk Fill Restorative 1- 4g A3.5 Shade Syringe - Instructions for Use
4866B1	Filtek One Bulk Fill Restorative 1- 4g B1 Shade Syringe - Instructions for Use
4866C2	Filtek One Bulk Fill Restorative 1- 4g C2 Shade Syringe - Instructions for Use
4866W	Filtek One Bulk Fill Restorative 1- 4g W Shade Syringe - Instructions for Use
Capsule Refills	
4867A1	Filtek One Bulk Fill Restorative 20 - 0.2g A1 Shade Capsules - Instructions for Use
4867A2	Filtek One Bulk Fill Restorative 20 - 0.2g A2 Shade Capsules - Instructions for Use
4867A3	Filtek One Bulk Fill Restorative 20 - 0.2g A3 Shade Capsules - Instructions for Use
4867A3.5	Filtek One Bulk Fill Restorative 20 - 0.2g A3.5 Shade Capsules - Instructions for Use
4867B1	Filtek One Bulk Fill Restorative 20 - 0.2g B1 Shade Capsules - Instructions for Use
4867C2	Filtek One Bulk Fill Restorative 20 - 0.2g C2 Shade Capsules - Instructions for Use
4867W	Filtek One Bulk Fill Restorative 20 - 0.2g W Shade Capsules - Instructions for Use
Samples	
4866A2-S	Filtek One Bulk Fill Restorative 1 – 1g A2 Shade Syringe - Instructions for Use
4867A2-S	Filtek One Bulk Fill Restorative 5 – 0.2g A2 Shade Capsules - Instructions for Use
4867A3-S	Filtek One Bulk Fill Restorative 5 – 0.2g A3 Shade Capsule

	• Instructions for Use
4866-SP	Efficient Restorative Procedure Solutions Pack • 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) • Instructions for Use
4867-CP	Efficient Restorative Procedure Solutions Pack • 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) • Instructions for Use
CEE/MEA/RUS	
Syringe Refills	
4870A1	Filtek One Bulk Fill Restorative • 1- 4g A1 Shade Syringe • Instructions for Use
4870A2	Filtek One Bulk Fill Restorative • 1- 4g A2 Shade Syringe • Instructions for Use
4870A3	Filtek One Bulk Fill Restorative • 1- 4g A3 Shade Syringe • Instructions for Use
4870A3.5	Filtek One Bulk Fill Restorative • 1- 4g A3.5 Shade Syringe • Instructions for Use
4870B1	Filtek One Bulk Fill Restorative • 1- 4g B1 Shade Syringe • Instructions for Use
4870C2	Filtek One Bulk Fill Restorative • 1- 4g C2 Shade Syringe • Instructions for Use
4870W	Filtek One Bulk Fill Restorative • 1- 4g W Shade Syringe • Instructions for Use
Capsule Refills	
4871A1	Filtek One Bulk Fill Restorative • 20 - 0.2g A1 Shade Capsules • Instructions for Use
4871A2	Filtek One Bulk Fill Restorative • 20 - 0.2g A2 Shade Capsules • Instructions for Use
4871A3	Filtek One Bulk Fill Restorative • 20 - 0.2g A3 Shade Capsules • Instructions for Use
4871A3.5	Filtek One Bulk Fill Restorative • 20 - 0.2g A3.5 Shade Capsules • Instructions for Use
4871B1	Filtek One Bulk Fill Restorative

	• 20 - 0.2g B1 Shade Capsules • Instructions for Use
4871C2	Filtek One Bulk Fill Restorative • 20 - 0.2g C2 Shade Capsules • Instructions for Use
4871W	Filtek One Bulk Fill Restorative • 20 - 0.2g W Shade Capsules • Instructions for Use
Samples	
4870A2-S	Filtek One Bulk Fill Restorative • 1 – 1g A2 Shade Syringe • Instructions for Use
4871A2-S	Filtek One Bulk Fill Restorative • 5 – 0.2g A2 Shade Capsules • Instructions for Use
4870-SP	Efficient Restorative Procedure Solutions Pack • 1 - 1g Filtek One Bulk Fill Restorative A2 Shade Syringe • 5 – Single Bond Universal Adhesive Unit Dose Applicators • Sof-Lex™ Diamond Polishing System 3 – Pre-polishing Spirals 3 – Diamond Polishing Spirals 1 – Mandrel (RA) • Instructions for Use
4871-CP	Efficient Restorative Procedure Solutions Pack • 5 – 0.2g Filtek One Bulk Fill Restorative A2 Shade Capsules • 5 – Single Bond Universal Adhesive Unit Dose Applicators • Sof-Lex™ Diamond Polishing System 3 – Pre-polishing Spirals 3 – Diamond Polishing Spirals 1 – Mandrel (RA) • Instructions for Use