



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: 3M™ Filtek™ Universal
Restorative
CE Mark Date: February 04, 2019

EC Product Class: IIa
Rule: 8

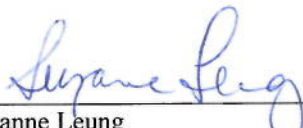
Per Annex IX of the Medical Device Directive

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 SD 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

04 Feb 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™ Universal Restorative

NA/WE/ANZ		
Catalog Number	Trade name/generic descriptor	Content / Quantity
Refills		
6555A1	Filtek Universal Restorative Syringe	1 - 4g A1 Shade Syringe Instructions for Use
6555A2	Filtek Universal Restorative Syringe	1 - 4g A2 Shade Syringe Instructions for Use
6555A3	Filtek Universal Restorative Syringe	1 - 4g A3 Shade Syringe Instructions for Use
6555A3.5	Filtek Universal Restorative Syringe	1 - 4g A3.5 Shade Syringe Instructions for Use
6555A4	Filtek Universal Restorative Syringe	1 - 4g A4 Shade Syringe Instructions for Use
6555B1	Filtek Universal Restorative Syringe	1 - 4g B1 Shade Syringe Instructions for Use
6555B2	Filtek Universal Restorative Syringe	1 - 4g B2 Shade Syringe Instructions for Use
6555D3	Filtek Universal Restorative Syringe	1 - 4g D3 Shade Syringe Instructions for Use
6555XW	Filtek Universal Restorative Syringe	1 - 4g XW Shade Syringe Instructions for Use
6555PO	Filtek Universal Restorative Syringe	1 - 4g PO Shade Syringe Instructions for Use
6550A1	Filtek Universal Restorative Capsules	20 - 0.2g A1 Shade Capsules Instructions for Use
6550A2	Filtek Universal Restorative Capsules	20 - 0.2g A2 Shade Capsules Instructions for Use
6550A3	Filtek Universal Restorative Capsules	20 - 0.2g A3 Shade Capsules Instructions for Use
6550A3.5	Filtek Universal Restorative Capsules	20 - 0.2g A3.5 Shade Capsules Instructions for Use
6550A4	Filtek Universal Restorative Capsules	20 - 0.2g A4 Shade Capsules Instructions for Use
6550B1	Filtek Universal Restorative Capsules	20 - 0.2g B1 Shade Capsules Instructions for Use
6550B2	Filtek Universal Restorative Capsules	20 - 0.2g B2 Shade Capsules Instructions for Use
6550D3	Filtek Universal Restorative Capsules	20 - 0.2g D3 Shade Capsules Instructions for Use
6550XW	Filtek Universal Restorative Capsules	20 - 0.2g XW Shade Capsules Instructions for Use
6550PO	Filtek Universal Restorative Capsules	10 - 0.2g PO Shade Capsules Instructions for Use
Samples		
6550A2-S	Filtek Universal Restorative Capsules	5 - 0.2g A2 Shade Capsules Instructions for Use
6550A3-S	Filtek Universal Restorative Capsules	5 - 0.2g A3 Shade Capsules Instructions for Use

NA/WE/ANZ		
Catalog Number	Trade name/generic descriptor	Content / Quantity
6555A2-S	Filtek Universal Restorative Syringe	1 - 1g A2 Shade Syringe Instructions for Use
6555A3-S	Filtek Universal Restorative Syringe	1 - 1g A3 Shade Syringe Instructions for Use
6550A2-CP	Filtek Universal Restorative Procedure Pack	5 - 0.2g 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
Kits		
6555-SK	Filtek Universal Restorative Syringe Kit	1 - 4g A1 Shade Syringe 1 - 4g A2 Shade Syringe 1 - 4g A3 Shade Syringe 1 - 4g A3.5 Shade Syringe 1 - 4g PO Shade Syringe Instructions for Use
6550-CK	Filtek Universal Restorative Capsule Kit	20 - 0.2g A1 Shade Capsules 20 - 0.2g A2 Shade Capsules 20 - 0.2g A3 Shade Capsules 20 - 0.2g A3.5 Shade Capsules 10 - 0.2g PO Shade Capsules Instructions for Use

CEE/MEA		
Catalog Number	Trade name/generic descriptor	Content / Quantity
Refills		
6570A1	Filtek Universal Restorative Syringe	1 - 4g A1 Shade Syringe Instructions for Use
6570A2	Filtek Universal Restorative Syringe	1 - 4g A2 Shade Syringe Instructions for Use
6570A3	Filtek Universal Restorative Syringe	1 - 4g A3 Shade Syringe Instructions for Use
6570A3.5	Filtek Universal Restorative Syringe	1 - 4g A3.5 Shade Syringe Instructions for Use
6570A4	Filtek Universal Restorative Syringe	1 - 4g A4 Shade Syringe Instructions for Use
6570B1	Filtek Universal Restorative Syringe	1 - 4g B1 Shade Syringe Instructions for Use
6570B2	Filtek Universal Restorative Syringe	1 - 4g B2 Shade Syringe Instructions for Use
6570D3	Filtek Universal Restorative Syringe	1 - 4g D3 Shade Syringe Instructions for Use
6570XW	Filtek Universal Restorative Syringe	1 - 4g XW Shade Syringe Instructions for Use
6570PO	Filtek Universal Restorative Syringe	1 - 4g PO Shade Syringe Instructions for Use
6575A1	Filtek Universal Restorative Capsules	20 - 0.2g A1 Shade Capsules Instructions for Use

CEE/MEA		
Catalog Number	Trade name/generic descriptor	Content / Quantity
6575A2	Filtek Universal Restorative Capsules	20 - 0.2g A2 Shade Capsules Instructions for Use
6575A3	Filtek Universal Restorative Capsules	20 - 0.2g A3 Shade Capsules Instructions for Use
6575A3.5	Filtek Universal Restorative Capsules	20 - 0.2g A3.5 Shade Capsules Instructions for Use
6575A4	Filtek Universal Restorative Capsules	20 - 0.2g A4 Shade Capsules Instructions for Use
6575B1	Filtek Universal Restorative Capsules	20 - 0.2g B1 Shade Capsules Instructions for Use
6575B2	Filtek Universal Restorative Capsules	20 - 0.2g B2 Shade Capsules Instructions for Use
6575D3	Filtek Universal Restorative Capsules	20 - 0.2g D3 Shade Capsules Instructions for Use
6575XW	Filtek Universal Restorative Capsules	20 - 0.2g XW Shade Capsules Instructions for Use
6575PO	Filtek Universal Restorative Capsules	10 - 0.2g PO Shade Capsules Instructions for Use
Samples		
6575A2-S	Filtek Universal Restorative Capsules	5 - 0.2g A2 Shade Capsules Instructions for Use
6575A3-S	Filtek Universal Restorative Capsules	5 - 0.2g A3 Shade Capsules Instructions for Use
6570A2-S	Filtek Universal Restorative Syringe	1 - 1g A2 Shade Syringe Instructions for Use
6570A3-S	Filtek Universal Restorative Syringe	1 - 1g A3 Shade Syringe Instructions for Use
6575A2-CP	Filtek Universal Restorative Procedure Pack	5 - 0.2g 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
Kits		
6570-SK	Filtek Universal Restorative Syringe Kit	1 - 4g A1 Shade Syringe 1 - 4g A2 Shade Syringe 1 - 4g A3 Shade Syringe 1 - 4g A3.5 Shade Syringe 1 - 4g PO Shade Syringe Instructions for Use
6575-CK	Filtek Universal Restorative Capsule Kit	20 - 0.2g A1 Shade Capsules 20 - 0.2g A2 Shade Capsules 20 - 0.2g A3 Shade Capsules 20 - 0.2g A3.5 Shade Capsules 10 - 0.2g PO Shade Capsules Instructions for Use