



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: Filtek™ Ultimate Universal
Restorative

CE Mark Date: Jan. 15, 2009

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 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


Gretchen E. Keenan

Manager
3M ESPE
Regulatory Affairs
Title

St. Paul, MN USA
Location

1 Mar 2017
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

♦ Filtek™ Ultimate Universal Restorative

Item	Catalogue/Order Number
Kits	
Filtek Ultimate Universal Restorative Syringe Single Shade Introductory Kit 4-4g syringes: 2 each of Body shades A2 and A3 Technique Guides Instructions for Use	3920S
Filtek Ultimate Universal Restorative Syringe Dual Shade Introductory Kit 4-4g syringes: 1 each of Dentin shades A3, A4, and Enamel shades A2,A3 1 Shade selection Wheel Technique Guides Instructions for Use	3920D
Filtek Ultimate Universal Restorative Syringe Professional Kit 12-4g syringes, 1 each of shades: Dentin shades: A2, A3, B3 Body shades: A2, A3, A3.5, B2 Enamel shades: A1, A2, A3, W Translucent shades: AT 1 Shade selection Wheel Technique Guides Instructions for Use	3920P
Filtek Ultimate Universal Restorative Professional Procedure Kit 12-4g syringes, 1 each of shades: Dentin shades: A2, A3, A4 Body shades: A2, A3, A3.5, A4 Enamel shades: A1, A2, A3, W Translucent shades: CT 1-5ml Single Bond Universal Adhesive 1-3ml Scotchbond™ Universal Etchant 25 Etchant dispensing tips 6 Sof-Lex™ Spiral Finishing Wheels (beige) 6 Sof-Lex™ Spiral Polishing Wheels (white) 1 RA Mandrel 1 Shade selection Wheel Instructions for Use	3920P-R
Filtek Ultimate Universal Restorative Single Shade Procedure Kit 4-4g syringes: 2 each of Body shades A2 and A3 1-5ml Single Bond Universal Adhesive 1-3ml Scotchbond™ Universal Etchant 25 Etchant dispensing tips Instructions for Use	3920S-R

Syringe Refills	
Filtek Ultimate Universal Restorative 1-4g A1 Dentin Shade Syringe Instructions for Use	3920A1D
Filtek Ultimate Universal Restorative 1-4g A2 Dentin Shade Syringe Instructions for Use	3920A2D
Filtek Ultimate Universal Restorative 1-4g A3 Dentin Shade Syringe Instructions for Use	3920A3D
Filtek Ultimate Universal Restorative 1-4g A4 Dentin Shade Syringe Instructions for Use	3920A4D
Filtek Ultimate Universal Restorative 1-4g B3 Dentin Shade Syringe Instructions for Use	3920B3D
Filtek Ultimate Universal Restorative 1-4g C4 Dentin Shade Syringe Instructions for Use	3920C4D
Filtek Ultimate Universal Restorative 1-4g W Dentin Shade Syringe Instructions for Use	3920WD
Filtek Ultimate Universal Restorative 1-4g A1 Body Shade Syringe Instructions for Use	3920A1B
Filtek Ultimate Universal Restorative 1-4g A2 Body Shade Syringe Instructions for Use	3920A2B
Filtek Ultimate Universal Restorative 1-4g A3 Body Shade Syringe Instructions for Use	3920A3B
Filtek Ultimate Universal Restorative 1-4g A3.5 Body Shade Syringe Instructions for Use	3920A3.5B
Filtek Ultimate Universal Restorative 1-4g A4 Body Shade Syringe Instructions for Use	3920A4B
Filtek Ultimate Universal Restorative 1-4g A6 Body Shade Syringe Instructions for Use	3920A6B
Filtek Ultimate Universal Restorative 1-4g B1 Body Shade Syringe Instructions for Use	3920B1B
Filtek Ultimate Universal Restorative 1-4g B2 Body Shade Syringe Instructions for Use	3920B2B
Filtek Ultimate Universal Restorative 1-4g B3 Body Shade Syringe Instructions for Use	3920B3B
Filtek Ultimate Universal Restorative 1-4g B5 Body Shade Syringe Instructions for Use	3920B5B
Filtek Ultimate Universal Restorative 1-4g C1 Body Shade Syringe Instructions for Use	3920C1B
Filtek Ultimate Universal Restorative 1-4g C2 Body Shade Syringe Instructions for Use	3920C2B

Filtek Ultimate Universal Restorative 1-4g C3 Body Shade Syringe Instructions for Use	3920C3B
Filtek Ultimate Universal Restorative 1-4g D2 Body Shade Syringe Instructions for Use	3920D2B
Filtek Ultimate Universal Restorative 1-4g D3 Body Shade Syringe Instructions for Use	3920D3B
Filtek Ultimate Universal Restorative 1-4g W Body Shade Syringe Instructions for Use	3920WB
Filtek Ultimate Universal Restorative 1-4g XW Body Shade Syringe Instructions for Use	3920XWB
Filtek Ultimate Universal Restorative 1-4g A1 Enamel Shade Syringe Instructions for Use	3920A1E
Filtek Ultimate Universal Restorative 1-4g A2 Enamel Shade Syringe Instructions for Use	3920A2E
Filtek Ultimate Universal Restorative 1-4g A3 Enamel Shade Syringe Instructions for Use	3920A3E
Filtek Ultimate Universal Restorative 1-4g B1 Enamel Shade Syringe Instructions for Use	3920B1E
Filtek Ultimate Universal Restorative 1-4g B2 Enamel Shade Syringe Instructions for Use	3920B2E
Filtek Ultimate Universal Restorative 1-4g D2 Enamel Shade Syringe Instructions for Use	3920D2E
Filtek Ultimate Universal Restorative 1-4g W Enamel Shade Syringe Instructions for Use	3920WE
Filtek Ultimate Universal Restorative 1-4g XW Enamel Shade Syringe Instructions for Use	3920XWE
Filtek Ultimate Universal Restorative 1-4g Clear Translucent Shade Syringe Instructions for Use	3920CT
Filtek Ultimate Universal Restorative 1-4g Blue Translucent Shade Syringe Instructions for Use	3920BT
Filtek Ultimate Universal Restorative 1-4g Grey Translucent Shade Syringe Instructions for Use	3920GT
Filtek Ultimate Universal Restorative 1-4g Amber Translucent Shade Syringe Instructions for Use	3920AT

Samples	
Filtek Ultimate Universal Restorative Syringe sample 1-1g syringe A2 Body shade in plastic bag Instructions for Use	3920A2B-S (Not for Sale)
Accessory	
Restorative Dispenser	5707SD