



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

Device Class: IIa per Rule VIII in Annex IX
of 93/42/EEC as amended by
2007/47/EC

Product(s): Filtek™ Ultimate Universal
Restorative

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
Kits	
3920S	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
3920D	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
3920P	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-R	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
3920S-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
Syringe Refills	
3920A1D	Filtek Ultimate Universal Restorative • 1-4g A1 Dentin Shade Syringe • Instructions for Use
3920A2D	Filtek Ultimate Universal Restorative • 1-4g A2 Dentin Shade Syringe • Instructions for Use
3920A3D	Filtek Ultimate Universal Restorative • 1-4g A3 Dentin Shade Syringe • Instructions for Use

3920A4D	Filtek Ultimate Universal Restorative • 1-4g A4 Dentin Shade Syringe • Instructions for Use
3920B3D	Filtek Ultimate Universal Restorative • 1-4g B3 Dentin Shade Syringe • Instructions for Use
3920C4D	Filtek Ultimate Universal Restorative • 1-4g C4 Dentin Shade Syringe • Instructions for Use
3920WD	Filtek Ultimate Universal Restorative • 1-4g W Dentin Shade Syringe • Instructions for Use
3920A1B	Filtek Ultimate Universal Restorative • 1-4g A1 Body Shade Syringe • Instructions for Use
3920A2B	Filtek Ultimate Universal Restorative • 1-4g A2 Body Shade Syringe • Instructions for Use
3920A3B	Filtek Ultimate Universal Restorative • 1-4g A3 Body Shade Syringe • Instructions for Use
3920A3.5B	Filtek Ultimate Universal Restorative • 1-4g A3.5 Body Shade Syringe • Instructions for Use
3920A4B	Filtek Ultimate Universal Restorative • 1-4g A4 Body Shade Syringe • Instructions for Use
3920A6B	Filtek Ultimate Universal Restorative • 1-4g A6 Body Shade Syringe • Instructions for Use
3920B1B	Filtek Ultimate Universal Restorative • 1-4g B1 Body Shade Syringe • Instructions for Use
3920B2B	Filtek Ultimate Universal Restorative • 1-4g B2 Body Shade Syringe • Instructions for Use
3920B3B	Filtek Ultimate Universal Restorative • 1-4g B3 Body Shade Syringe • Instructions for Use
3920B5B	Filtek Ultimate Universal Restorative • 1-4g B5 Body Shade Syringe • Instructions for Use
3920C1B	Filtek Ultimate Universal Restorative • 1-4g C1 Body Shade Syringe • Instructions for Use
3920C2B	Filtek Ultimate Universal Restorative • 1-4g C2 Body Shade Syringe • Instructions for Use
3920C3B	Filtek Ultimate Universal Restorative • 1-4g C3 Body Shade Syringe • Instructions for Use
3920D2B	Filtek Ultimate Universal Restorative • 1-4g D2 Body Shade Syringe • Instructions for Use
3920D3B	Filtek Ultimate Universal Restorative • 1-4g D3 Body Shade Syringe • Instructions for Use
3920WB	Filtek Ultimate Universal Restorative

	• 1-4g W Body Shade Syringe • Instructions for Use
3920XWB	Filtek Ultimate Universal Restorative • 1-4g XW Body Shade Syringe • Instructions for Use
3920A1E	Filtek Ultimate Universal Restorative • 1-4g A1 Enamel Shade Syringe • Instructions for Use
3920A2E	Filtek Ultimate Universal Restorative • 1-4g A2 Enamel Shade Syringe • Instructions for Use
3920A3E	Filtek Ultimate Universal Restorative • 1-4g A3 Enamel Shade Syringe • Instructions for Use
3920B1E	Filtek Ultimate Universal Restorative • 1-4g B1 Enamel Shade Syringe • Instructions for Use
3920B2E	Filtek Ultimate Universal Restorative • 1-4g B2 Enamel Shade Syringe • Instructions for Use
3920D2E	Filtek Ultimate Universal Restorative • 1-4g D2 Enamel Shade Syringe • Instructions for Use
3920WE	Filtek Ultimate Universal Restorative • 1-4g W Enamel Shade Syringe • Instructions for Use
3920XWE	Filtek Ultimate Universal Restorative • 1-4g XW Enamel Shade Syringe • Instructions for Use
3920CT	Filtek Ultimate Universal Restorative • 1-4g Clear Translucent Shade Syringe • Instructions for Use
3920BT	Filtek Ultimate Universal Restorative • 1-4g Blue Translucent Shade Syringe • Instructions for Use
3920GT	Filtek Ultimate Universal Restorative • 1-4g Grey Translucent Shade Syringe • Instructions for Use
3920AT	Filtek Ultimate Universal Restorative • 1-4g Amber Translucent Shade Syringe • Instructions for Use
Samples	
3920A2B-S (Not for Sale)	Filtek Ultimate Universal Restorative Syringe sample • 1-1g syringe A2 Body shade, in plastic bag • Instructions for Use