



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): Filtek™ Z250 Universal
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
Global Regulatory Affairs Director
3M ESPE Dental Products

November 16, 2022

Date

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Item Number	Description
Kits Eastern Europe	
6020E	Filtek Z250 Universal Restorative System • 8 x 4 g Restorative Paste • 3 ml syringe Scotchbond™ Universal Etchant • 6 g Adper™ Single Bond 2 Adhesive • 25 Etchant dispensing tips • 25 fiber tips • 2 brush handles • 48 mixing wells • 1 mix pad • 1 Sof-lex™ Finishing and Polishing System • 1 shade guide • Instructions for use
6020TK	Filtek Z250 Universal Restorative Trial Kit • 4 x 4 g Restorative Paste • 3 ml syringe Scotchbond™ Universal Etchant • 6 g Adper™ Single Bond 2 Adhesive • 25 Etchant dispensing tips • 25 fiber tips • 2 brush handles • 48 mixing wells • 1 mix pad • 1 shade guide • Instructions for use
Kits Western Europe	
6020	Filtek Z250 Universal Restorative System • 4 x 4g Restorative Paste • 3 ml Scotchbond™ Universal Etchant • 3 g Adper™ Scotchbond™ 1XT Adhesive • 25 Etchant dispensing tips • 25 fiber tips • 2 brush handles • 48 mixing wells • 1 mix pad • 1 Sof-lex™ Finishing and Polishing System • 1 shade guide • Instructions for use
Syringe Refills Eastern and Western Europe	
6020A1	Filtek Z250 Universal Restorative A1 Shade • 1 each - 4 g syringe • Instructions for use
6020A2	Filtek Z250 Universal Restorative A2 Shade • 1 each - 4 g syringe • Instructions for use
6020A2	Filtek Z250 Universal Restorative A2 Shade • 1 each - 1 g syringe • Instructions for use
6020A3	Filtek Z250 Universal Restorative A3 Shade • 1 each - 4 g syringe • Instructions for use

6020A3.5	Filtek Z250 Universal Restorative A3.5 Shade • 1 each - 4 g syringe • Instructions for use
6020A4	Filtek Z250 Universal Restorative A4 Shade • 1 each - 4 g syringe • Instructions for use
6020B1	Filtek Z250 Universal Restorative B1 Shade • 1 each - 4 g syringe • Instructions for use
6020B2	Filtek Z250 Universal Restorative B2 Shade • 1 each - 4 g syringe • Instructions for use
6020B3	Filtek Z250 Universal Restorative B3 Shade • 1 each - 4 g syringe • Instructions for use
6020C2	Filtek Z250 Universal Restorative C2 Shade • 1 each - 4 g syringe • Instructions for use
6020D3	Filtek Z250 Universal Restorative D3 Shade • 1 each - 4 g syringe • Instructions for use
6020I	Filtek Z250 Universal Restorative Incisal Shade • 1 each - 4 g syringe • Instructions for use
6020UD	Filtek Z250 Universal Restorative Universal Dentin Shade • 1 each - 4 g syringe • Instructions for use
Capsule refills Western Europe only	
6021A1	Filtek Z250 Universal Restorative A1 Shade • 20 each - 0.2 g Capsule • Instructions for use
6021A2	Filtek Z250 Universal Restorative A2 Shade • 20 each - 0.2 g Capsule • Instructions for use
6021A3	Filtek Z250 Universal Restorative A3 Shade • 20 each - 0.2 g Capsule • Instructions for use
6021A3.5	Filtek Z250 Universal Restorative A3.5 Shade • 20 each - 0.2 g Capsule • Instructions for use
6021A4	Filtek Z250 Universal Restorative A4 Shade • 20 each - 0.2 g Capsule • Instructions for use
6021B1	Filtek Z250 Universal Restorative B1 Shade • 20 each - 0.2 g Capsule • Instructions for use
6021B2	Filtek Z250 Universal Restorative B2 Shade • 20 each - 0.2 g Capsule • Instructions for use
6021B3	Filtek Z250 Universal Restorative B3 Shade • 20 each - 0.2 g Capsule • Instructions for use

6021C2		Filtek Z250 Universal Restorative C2 Shade • 20 each - 0.2 g Capsule • Instructions for use
6021D3		Filtek Z250 Universal Restorative D3 Shade • 20 each - 0.2 g Capsule • Instructions for use
6021I		Filtek Z250 Universal Restorative Incisal Shade • 20 each - 0.2 g Capsule • Instructions for use
6021UD		Filtek Z250 Universal Restorative Universal Dentin Shade • 20 each - 0.2 g Capsule • Instructions for use