



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™ Z250 Universal
Restorative

CE Mark Date: December, 2001

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

Date

2 Mar 2017

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™ Z250 Universal Restorative

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
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
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
Accessory	
5707SD	Restorative Dispenser

	Middle East
Kits	
1370L	Filtek Z250 Universal Restorative System ◆ 4 x4 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
1370KSA	Filtek Z250 Universal Restorative System ◆ 6 x4 g Restorative Paste ◆ 3 ml syringe Scotchbond™ Universal Etchant ◆ 5 ml Single Bond Universal Adhesive ◆ 25 Etchant dispensing tips ◆ 25 fiber tips ◆ Instructions for use
Refills	
1370A1	Filtek Z250 Universal Restorative A1 Shade ◆ 1 each - 4 g syringe ◆ Instructions for use
1370A2	Filtek Z250 Universal Restorative A2 Shade ◆ 1 each - 4 g syringe ◆ Instructions for use
1370A3	Filtek Z250 Universal Restorative A3 Shade ◆ 1 each - 4 g syringe ◆ Instructions for use
1370A3.5	Filtek Z250 Universal Restorative A3.5 Shade ◆ 1 each - 4 g syringe ◆ Instructions for use
1370A4	Filtek Z250 Universal Restorative A4 Shade ◆ 1 each - 4 g syringe ◆ Instructions for use
1370B1	Filtek Z250 Universal Restorative B1 Shade ◆ 1 each - 4 g syringe ◆ Instructions for use
1370B2	Filtek Z250 Universal Restorative B2 Shade ◆ 1 each - 4 g syringe ◆ Instructions for use
1370B3	Filtek Z250 Universal Restorative B3 Shade ◆ 1 each - 4 g syringe ◆ Instructions for use
1370C2	Filtek Z250 Universal Restorative C2 Shade ◆ 1 each - 4 g syringe ◆ Instructions for use
1370D3	Filtek Z250 Universal Restorative D3 Shade ◆ 1 each - 4 g syringe ◆ Instructions for use
1370I	Filtek Z250 Universal Restorative Incisal Shade ◆ 1 each - 4 g syringe ◆ Instructions for use
1370UD	Filtek Z250 Universal Restorative Universal Dentin Shade ◆ 1 each - 4 g syringe ◆ Instructions for use