3M ESPE
Dental Products

2510 Conway Avenue
St. Paul, MN 55144 USA

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™ Z550 Nano Hybrid Universal Restorative

CE Mark Date: Sept. 23, 2010

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	St. Paul, MN USA	2 Mar 2017
	Title	Location	Date

Revision 17Nov2016

EC DECLARATION OF CONFORMITY

Product Family: Resin-Based Restorative Materials
Device Description: Non-Sterile Dental Restorative Material
EC Product Class (Per Annex IX Rules): Class: IIa Rule:8
Product:
- Filtek™ Z550 Nano Hybrid Universal Restorative

Item	Catalogue/Order Number
Kits	
Filtek Z550 Nano Hybrid Universal Restorative Trial Kit • 4 x 4g (1 each: shades A2, A3, A3.5, OA2) • 1 x 6g Adper™ Single Bond 2 Adhesive • 1 x 3ml Syringe Scotchbond™ Universal Etchant • 25 etchant dispensing tips • 25 fiber tips • 1 brush handle • 1 mix well • Technique guide(s) • Instructions For Use	7050TK
Filtek Z550 Nano Hybrid Universal Restorative Intro Kit • 8 x 4g (1 each: Shades A1, A2, A3, A3.5, B3, C2, D3, OA2) • 1 x 6g Adper ™ Single Bond 2 Adhesive • 1 x 3ml Syringe Scotchbond™ Universal Etchant • 25 etchant dispensing tips • 25 fiber tips • 1 brush handle • 1 mix well • Technique guide(s) • Instructions For Use	7050IK
Syringe Refills	
Filtek Z550 Nano Hybrid Universal Restorative • 1 x 4g A1 Shade Syringe • Instructions for Use	7050A1
Filtek Z550 Nano Hybrid Universal Restorative • 1 x 4g A2 Shade Syringe • Instructions for Use	7050A2
Filtek Z550 Nano Hybrid Universal Restorative • 1 x 4g A3 Shade Syringe • Instructions for Use	7050A3
Filtek Z550 Nano Hybrid Universal Restorative • 1 x 4g A3.5 Shade Syringe • Instructions for Use	7050A3.5
Filtek Z550 Nano Hybrid Universal Restorative • 1 x 4g A4 Shade Syringe • Instructions for Use	7050A4
Filtek Z550 Nano Hybrid Universal Restorative • 1 x 4g B1 Shade Syringe • Instructions for Use	7050B1

Filtek Z550 Nano Hybrid Universal Restorative • 1 x 4g B2 Shade Syringe • Instructions for Use	7050B2
Filtek Z550 Nano Hybrid Universal Restorative • 1 x 4g B3 Shade Syringe • Instructions for Use	7050B3
Filtek Z550 Nano Hybrid Universal Restorative • 1 x 4g C2 Shade Syringe • Instructions for Use	7050C2
Filtek Z550 Nano Hybrid Universal Restorative • 1 x 4g D3 Shade Syringe • Instructions for Use	7050D3
Filtek Z550 Nano Hybrid Universal Restorative • 1 x 4g OA2 Shade Syringe • Instructions for Use	7050OA2
Filtek Z550 Nano Hybrid Universal Restorative • 1 x 4g OA3 Shade Syringe • Instructions for Use	7050OA3
Samples	
Filtek Z550 Nano Hybrid Universal Restorative • 1 x 1g A2 Shade Syringe • Instructions for Use	7050A2-S Not for Sale