



**EC DECLARATION OF CONFORMITY**

Annex II, Clause 3 of Council Directive 93/42/EEC concerning Medical Devices.

**Manufacturer:**

3M ESPE Dental Products  
3M Center, Bldg 260  
St. Paul, Minnesota 55144-1000  
USA

EC Certificate No: G1 11 11 45735 020  
Valid until: 2016-12-03

GMDN CODE : 35875

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

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**Declaration of Conformity**

3M ESPE Dental Products declares that 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, 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

  
Signature

Director - 3M ESPE  
Regulatory Affairs St. Paul, Minnesota USA 2 April 2012  
Title Location Date

## 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
<b>Kits</b>	
Filtek Z550 Nano Hybrid Universal Restorative Trial Kit <ul style="list-style-type: none"> <li>• 4 x 4g (1 each: shades A2, A3, A3.5, OA2)</li> <li>• 1 x 6g Adper™ Single Bond 2 Adhesive</li> <li>• 1 x 3ml Syringe Scotchbond™ Etchant</li> <li>• 25 etchant dispensing tips</li> <li>• 25 fiber tips</li> <li>• 1 brush handle</li> <li>• 1 mix well</li> <li>• Technique guide(s)</li> <li>• Instructions For Use</li> </ul>	7050TK
Filtek Z550 Nano Hybrid Universal Restorative Intro Kit <ul style="list-style-type: none"> <li>• 8 x 4g (1 each: Shades A1, A2, A3, A3.5, B3, C2, D3, OA2)</li> <li>• 1 x 6g Adper™ Single Bond 2 Adhesive</li> <li>• 1 x 3ml Syringe Scotchbond™ Etchant</li> <li>• 25 etchant dispensing tips</li> <li>• 25 fiber tips</li> <li>• 1 brush handle</li> <li>• 1 mix well</li> <li>• Technique guide(s)</li> <li>• Instructions For Use</li> </ul>	7050IK
<b>Syringe Refills</b>	
Filtek Z550 Nano Hybrid Universal Restorative <ul style="list-style-type: none"> <li>• 1 x 4g A1 Shade Syringe</li> <li>• Instructions for Use</li> </ul>	7050A1
Filtek Z550 Nano Hybrid Universal Restorative <ul style="list-style-type: none"> <li>• 1 x 4g A2 Shade Syringe</li> <li>• Instructions for Use</li> </ul>	7050A2
Filtek Z550 Nano Hybrid Universal Restorative <ul style="list-style-type: none"> <li>• 1 x 4g A3 Shade Syringe</li> <li>• Instructions for Use</li> </ul>	7050A3
Filtek Z550 Nano Hybrid Universal Restorative <ul style="list-style-type: none"> <li>• 1 x 4g A3.5 Shade Syringe</li> <li>• Instructions for Use</li> </ul>	7050A3.5
Filtek Z550 Nano Hybrid Universal Restorative <ul style="list-style-type: none"> <li>• 1 x 4g A4 Shade Syringe</li> <li>• Instructions for Use</li> </ul>	7050A4
Filtek Z550 Nano Hybrid Universal Restorative <ul style="list-style-type: none"> <li>• 1 x 4g B1 Shade Syringe</li> <li>• Instructions for Use</li> </ul>	7050B1

Filtek Z550 Nano Hybrid Universal Restorative <ul style="list-style-type: none"> <li>• 1 x 4g B2 Shade Syringe</li> <li>• Instructions for Use</li> </ul>	7050B2
Filtek Z550 Nano Hybrid Universal Restorative <ul style="list-style-type: none"> <li>• 1 x 4g B3 Shade Syringe</li> <li>• Instructions for Use</li> </ul>	7050B3
Filtek Z550 Nano Hybrid Universal Restorative <ul style="list-style-type: none"> <li>• 1 x 4g C2 Shade Syringe</li> <li>• Instructions for Use</li> </ul>	7050C2
Filtek Z550 Nano Hybrid Universal Restorative <ul style="list-style-type: none"> <li>• 1 x 4g D3 Shade Syringe</li> <li>• Instructions for Use</li> </ul>	7050D3
Filtek Z550 Nano Hybrid Universal Restorative <ul style="list-style-type: none"> <li>• 1 x 4g OA2 Shade Syringe</li> <li>• Instructions for Use</li> </ul>	7050OA2
Filtek Z550 Nano Hybrid Universal Restorative <ul style="list-style-type: none"> <li>• 1 x 4g OA3 Shade Syringe</li> <li>• Instructions for Use</li> </ul>	7050OA3
<b>Samples</b>	
Filtek Z550 Nano Hybrid Universal Restorative <ul style="list-style-type: none"> <li>• 1 x 1g A2 Shade Syringe</li> <li>• Instructions for Use</li> </ul>	7050A2-S Not for Sale