3M ESPE
Dental Products

2510 Conway Avenue
St. Paul, MN 55144-1000

Truthful and Accurate Statement

This is to certify that the attached document is a copy of the EC Declaration of Conformity.

Product:

FILTEK™ Z550

Suzanne Leung — 27 Jan 2022

Suzanne Leung
Regulatory Affairs Director
3M Oral Care

Date

State of Minnesota)
County of Ramsey) SS

Subscribed and sworn to before me this 27 day of January 2022.

Ka Lia Xiong, Notary Public
My Commission Expires January 31st 2023

KA LIA XIONG
Notary Public
Minnesota
My Commission Expires January 31, 2023

3M ESPE
Dental Products

2510 Conway Avenue
St. Paul, MN 55144 USA

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™ Z550 Nano Hybrid 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

Suzanne Leung, PhD., RAC
Regulatory Affairs Director
3M ESPE Dental Products

08 July 2021

Date

EC DECLARATION OF CONFORMITY

Item Number	Description
Kits	
7050TK	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
7050IK	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
Syringe Refills	
7050A1	Filtek Z550 Nano Hybrid Universal Restorative • 1 x 4g A1 Shade Syringe • Instructions for Use
7050A2	Filtek Z550 Nano Hybrid Universal Restorative • 1 x 4g A2 Shade Syringe • Instructions for Use
7050A3	Filtek Z550 Nano Hybrid Universal Restorative • 1 x 4g A3 Shade Syringe • Instructions for Use
7050A3.5	Filtek Z550 Nano Hybrid Universal Restorative • 1 x 4g A3.5 Shade Syringe • Instructions for Use
7050A4	Filtek Z550 Nano Hybrid Universal Restorative • 1 x 4g A4 Shade Syringe • Instructions for Use
7050B1	Filtek Z550 Nano Hybrid Universal Restorative • 1 x 4g B1 Shade Syringe • Instructions for Use
7050B2	Filtek Z550 Nano Hybrid Universal Restorative • 1 x 4g B2 Shade Syringe • Instructions for Use
7050B3	Filtek Z550 Nano Hybrid Universal Restorative • 1 x 4g B3 Shade Syringe • Instructions for Use
7050C2	Filtek Z550 Nano Hybrid Universal Restorative • 1 x 4g C2 Shade Syringe • Instructions for Use
7050D3	Filtek Z550 Nano Hybrid Universal Restorative • 1 x 4g D3 Shade Syringe • Instructions for Use
7050OA2	Filtek Z550 Nano Hybrid Universal Restorative • 1 x 4g OA2 Shade Syringe

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