



**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

**Manufacturing Facility:**

3M ESPE Dental Products  
2111 McGaw Avenue  
Irvine, California 92614  
USA

Product Family: Resin-Based Restorative  
Materials

Product: Filtek™ Z500 Universal  
Restorative

EC Product Class: IIa  
Rule: 8

Per Annex IX of the Medical Device Directive

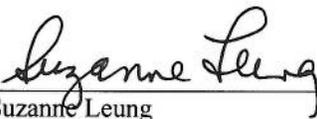
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**Declaration of Conformity**

3M ESPE Dental Products 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 13485:2016, 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

  
Suzanne Leung

Manager  
3M ESPE  
Regulatory Affairs  
Title

St. Paul, MN USA  
Location

09 Sep 2019  
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™ Z500 Universal Restorative

Kits	Description
8021TP	Filtek Z500 Universal Restorative – Starter Kit ♦ 60 - .2g capsules, 20 each of 3 different shades. ♦ Technique Guides ♦ Instructions for Use
8020TP	Filtek Z500 Universal Restorative – Starter Kit ♦ 3 - 3g syringes, 1 each of 3 different shades ♦ Technique Guides ♦ Instructions for Use
Capsule Refills	Description
8021A1	♦ 20 - .2g Filtek Z500 Universal Restorative A1 Shade Capsules ♦ Instructions for Use
8021A2	♦ 20 - .2g Filtek Z500 Universal Restorative A2 Shade Capsules ♦ Instructions for Use
8021A3	♦ 20 - .2g Filtek Z500 Universal Restorative A3 Shade Capsules ♦ Instructions for Use
8021A3.5	♦ 20 - .2g Filtek Z500 Universal Restorative A3.5 Shade Capsules ♦ Instructions for Use
8021A4	♦ 20 - .2g Filtek Z500 Universal Restorative A4 Shade Capsules ♦ Instructions for Use
8021B2	♦ 20 - .2g Filtek Z500 Universal Restorative B2 Shade Capsules ♦ Instructions for Use
8021C2	♦ 20 - .2g Filtek Z500 Universal Restorative C2 Shade Capsules ♦ Instructions for Use
8021D2	♦ 20 - .2g Filtek Z500 Universal Restorative D2 Shade Capsules ♦ Instructions for Use
8021OA3	♦ 20 - .2g Filtek Z500 Universal Restorative Opaque A3 Shade Capsules ♦ Instructions for Use
8021A3-S	♦ 5 - .2g Filtek Z500 Universal Restorative A3 Shade Capsules ♦ Instructions for Use
Syringe Refills	Description
8020A1	♦ 1 - 3g Filtek Z500 Universal Restorative A1 Shade Syringe ♦ Instructions for Use
8020A2	♦ 1 - 3g Filtek Z500 Universal Restorative A2 Shade Syringe ♦ Instructions for Use
8020A3	♦ 1 - 3g Filtek Z500 Universal Restorative A3 Shade Syringe ♦ Instructions for Use
8020A3.5	♦ 1 - 3g Filtek Z500 Universal Restorative A3.5 Shade Syringe ♦ Instructions for Use
8020A4	♦ 1 - 3g Filtek Z500 Universal Restorative A4 Shade Syringe ♦ Instructions for Use
8020B2	♦ 1 - 3g Filtek Z500 Universal Restorative B2 Shade Syringe ♦ Instructions for Use
8020C2	♦ 1 - 3g Filtek Z500 Universal Restorative C2 Shade Syringe ♦ Instructions for Use
8020D2	♦ 1 - 3g Filtek Z500 Universal Restorative D2 Shade Syringe

	◆ Instructions for Use
8020OA3	◆ 1 - 3g Filtek Z500 Universal Restorative Opaque A3 Shade Syringe ◆ Instructions for Use
8020A3-S	◆ 1 - 1g Filtek Z500 Universal Restorative A3 Shade Syringe ◆ Instructions for Use