



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™ Supreme XTE
Universal Restorative

EC Product Class: IIa
Rule: 8

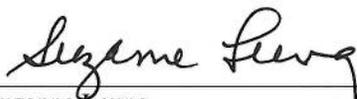
Per Annex IX of the Medical Device Directive

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 13485:2016, 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™ Supreme XTE Universal Restorative

ANZ

Item	Catalogue/Order Number
Kits	
Filtek Supreme XTE Universal Restorative Capsule Single Shade Introductory Kit 40-0.2g capsules: 20 each of Body shades A2 and A3 Technique Guides Instructions for Use	5915S
Filtek Supreme XTE Universal Restorative Syringe Single Shade Introductory Kit 4-4g syringes: 2 each of Body shades A2 and A3 Technique Guides Instructions for Use	5914S
Filtek Supreme XTE Universal Restorative Capsule Professional Kit 160-0.2g capsules: 10 ea of Dentin shades: A2, A3, A4 20 each of Body shades: A2, A3, A3.5, A4 10 each of Enamel shades: A1, A2, A3, W 10 each of Translucent shades: AT In plastic reusable case 1 Shade selection Wheel Technique Guides Instructions for Use	4911P (This kit is to support launch only and will not be sold to customers)
Capsule Refills	
Filtek Supreme XTE Universal Restorative 10 - 0.2g A1 Dentin Shade Capsules Instructions for Use	5915A1D
Filtek Supreme XTE Universal Restorative 10 - 0.2g A2 Dentin Shade Capsules Instructions for Use	5915A2D
Filtek Supreme XTE Universal Restorative 10 - 0.2g A3 Dentin Shade Capsules Instructions for Use	5915A3D
Filtek Supreme XTE Universal Restorative 10 - 0.2g A4 Dentin Shade Capsules Instructions for Use	5915A4D
Filtek Supreme XTE Universal Restorative 10 - 0.2g B3 Dentin Shade Capsules Instructions for Use	5915B3D
Filtek Supreme XTE Universal Restorative 10 - 0.2g C4 Dentin Shade Capsules Instructions for Use	5915C4D

Filtek Supreme XTE Universal Restorative 10 - 0.2g W Dentin Shade Capsules Instructions for Use	5915WD
Filtek Supreme XTE Universal Restorative 20 - 0.2g A1 Body Shade Capsules Instructions for Use	5915A1B
Filtek Supreme XTE Universal Restorative 20 - 0.2g A2 Body Shade Capsules Instructions for Use	5915A2B
Filtek Supreme XTE Universal Restorative 20 - 0.2g A3 Body Shade Capsules Instructions for Use	5915A3B
Filtek Supreme XTE Universal Restorative 20 - 0.2g A3.5 Body Shade Capsules Instructions for Use	5915A3.5B
Filtek Supreme XTE Universal Restorative 20 - 0.2g A4 Body Shade Capsules Instructions for Use	5915A4B
Filtek Supreme XTE Universal Restorative 20 - 0.2g A6 Body Shade Capsules Instructions for Use	5915A6B
Filtek Supreme XTE Universal Restorative 20 - 0.2g B1 Body Shade Capsules Instructions for Use	5915B1B
Filtek Supreme XTE Universal Restorative 20 - 0.2g B2 Body Shade Capsules Instructions for Use	5915B2B
Filtek Supreme XTE Universal Restorative 20 - 0.2g B3 Body Shade Capsules Instructions for Use	5915B3B
Filtek Supreme XTE Universal Restorative 20 - 0.2g B5 Body Shade Capsules Instructions for Use	5915B5B
Filtek Supreme XTE Universal Restorative 20 - 0.2g C1 Body Shade Capsules Instructions for Use	5915C1B
Filtek Supreme XTE Universal Restorative 20 - 0.2g C2 Body Shade Capsules Instructions for Use	5915C2B
Filtek Supreme XTE Universal Restorative 20 - 0.2g C3 Body Shade Capsules Instructions for Use	5915C3B
Filtek Supreme XTE Universal Restorative 20 - 0.2g D2 Body Shade Capsules Instructions for Use	5915D2B
Filtek Supreme XTE Universal Restorative 20 - 0.2g D3 Body Shade Capsules Instructions for Use	5915D3B
Filtek Supreme XTE Universal Restorative 20 - 0.2g W Body Shade Capsules Instructions for Use	5915WB
Filtek Supreme XTE Universal Restorative 20 - 0.2g XW Body Shade Capsules Instructions for Use	5915XWB
Filtek Supreme XTE Universal Restorative 10 - 0.2g A1 Enamel Shade Capsules Instructions for Use	5915A1E

Filtek Supreme XTE Universal Restorative 10 - 0.2g A2 Enamel Shade Capsules Instructions for Use	5915A2E
Filtek Supreme XTE Universal Restorative 10 - 0.2g A3 Enamel Shade Capsules Instructions for Use	5915A3E
Filtek Supreme XTE Universal Restorative 10 - 0.2g B1 Enamel Shade Capsules Instructions for Use	5915B1E
Filtek Supreme XTE Universal Restorative 10 - 0.2g B2 Enamel Shade Capsules Instructions for Use	5915B2E
Filtek Supreme XTE Universal Restorative 10 - 0.2g D2 Enamel Shade Capsules Instructions for Use	5915D2E
Filtek Supreme XTE Universal Restorative 10 - 0.2g W Enamel Shade Capsules Instructions for Use	5915WE
Filtek Supreme XTE Universal Restorative 10 - 0.2g XW Enamel Shade Capsules Instructions for Use	5915XWE
Filtek Supreme XTE Universal Restorative 10 - 0.2g Clear Translucent Shade Capsules Instructions for Use	5915CT
Filtek Supreme XTE Universal Restorative 10 - 0.2g Blue Translucent Shade Capsules Instructions for Use	5915BT
Filtek Supreme XTE Universal Restorative 10 - 0.2g Grey Translucent Shade Capsules Instructions for Use	5915GT
Filtek Supreme XTE Universal Restorative 10 - 0.2g Amber Translucent Shade Capsules Instructions for Use	5915AT
Syringe Refills	
Filtek Supreme XTE Universal Restorative 1-4g A1 Dentin Shade Syringe Instructions for Use	5914A1D
Filtek Supreme XTE Universal Restorative 1-4g A2 Dentin Shade Syringe Instructions for Use	5914A2D
Filtek Supreme XTE Universal Restorative 1-4g A3 Dentin Shade Syringe Instructions for Use	5914A3D
Filtek Supreme XTE Universal Restorative 1-4g A4 Dentin Shade Syringe Instructions for Use	5914A4D
Filtek Supreme XTE Universal Restorative 1-4g B3 Dentin Shade Syringe Instructions for Use	5914B3D
Filtek Supreme XTE Universal Restorative 1-4g C4 Dentin Shade Syringe Instructions for Use	5914C4D
Filtek Supreme XTE Universal Restorative 1-4g W Dentin Shade Syringe Instructions for Use	5914WD

Filtek Supreme XTE Universal Restorative 1-4g A1 Body Shade Syringe Instructions for Use	5914A1B
Filtek Supreme XTE Universal Restorative 1-4g A2 Body Shade Syringe Instructions for Use	5914A2B
Filtek Supreme XTE Universal Restorative 1-4g A3 Body Shade Syringe Instructions for Use	5914A3B
Filtek Supreme XTE Universal Restorative 1-4g A3.5 Body Shade Syringe Instructions for Use	5914A3.5B
Filtek Supreme XTE Universal Restorative 1-4g A4 Body Shade Syringe Instructions for Use	5914A4B
Filtek Supreme XTE Universal Restorative 1-4g A6 Body Shade Syringe Instructions for Use	5914A6B
Filtek Supreme XTE Universal Restorative 1-4g B1 Body Shade Syringe Instructions for Use	5914B1B
Filtek Supreme XTE Universal Restorative 1-4g B2 Body Shade Syringe Instructions for Use	5914B2B
Filtek Supreme XTE Universal Restorative 1-4g B3 Body Shade Syringe Instructions for Use	5914B3B
Filtek Supreme XTE Universal Restorative 1-4g B5 Body Shade Syringe Instructions for Use	5914B5B
Filtek Supreme XTE Universal Restorative 1-4g C1 Body Shade Syringe Instructions for Use	5914C1B
Filtek Supreme XTE Universal Restorative 1-4g C2 Body Shade Syringe Instructions for Use	5914C2B
Filtek Supreme XTE Universal Restorative 1-4g C3 Body Shade Syringe Instructions for Use	5914C3B
Filtek Supreme XTE Universal Restorative 1-4g D2 Body Shade Syringe Instructions for Use	5914D2B
Filtek Supreme XTE Universal Restorative 1-4g D3 Body Shade Syringe Instructions for Use	5914D3B
Filtek Supreme XTE Universal Restorative 1-4g W Body Shade Syringe Instructions for Use	5914WB
Filtek Supreme XTE Universal Restorative 1-4g XW Body Shade Syringe Instructions for Use	5914XWB
Filtek Supreme XTE Universal Restorative 1-4g A1 Enamel Shade Syringe Instructions for Use	5914A1E
Filtek Supreme XTE Universal Restorative 1-4g A2 Enamel Shade Syringe Instructions for Use	5914A2E

Filtek Supreme XTE Universal Restorative 1-4g A3 Enamel Shade Syringe Instructions for Use	5914A3E
Filtek Supreme XTE Universal Restorative 1-4g B1 Enamel Shade Syringe Instructions for Use	5914B1E
Filtek Supreme XTE Universal Restorative 1-4g B2 Enamel Shade Syringe Instructions for Use	5914B2E
Filtek Supreme XTE Universal Restorative 1-4g D2 Enamel Shade Syringe Instructions for Use	5914D2E
Filtek Supreme XTE Universal Restorative 1-4g W Enamel Shade Syringe Instructions for Use	5914WE
Filtek Supreme XTE Universal Restorative 1-4g XW Enamel Shade Syringe Instructions for Use	5914XWE
Filtek Supreme XTE Universal Restorative 1-4g Clear Translucent Shade Syringe Instructions for Use	5914CT
Filtek Supreme XTE Universal Restorative 1-4g Blue Translucent Shade Syringe Instructions for Use	5914BT
Filtek Supreme XTE Universal Restorative 1-4g Grey Translucent Shade Syringe Instructions for Use	5914GT
Filtek Supreme XTE Universal Restorative 1-4g Amber Translucent Shade Syringe Instructions for Use	5914AT
Samples	
Filtek Supreme XTE Universal Restorative Capsule sample 5-0.2g capsules A2 Body shade in plastic bottle Instructions for Use	5915A2B-S (Not for Sale)
Filtek Supreme XTE Universal Restorative Syringe sample 1-1g syringe A3 Body shade in plastic bag Instructions for Use	5914A3B-S (Not for Sale)
Esthetic Restoration Solution Pack 5 - 0.2g capsules Filtek Supreme XTE Universal Restorative A3 Body shade 5 - Scotchbond™ Universal Adhesive unit dose applicators Sof-Lex™ Diamond Polishing System 3 – Pre-polishing Spirals 3 – Polishing Spirals 1 – Mandrel (RA) Instructions for Use	6029CP (Not for Sale)