EUROPEAN MEDICAL DEVICE REGULATION

Declaration of Conformity

As Legal Manufacturer, we

3M Company, ESPE Dental Products
Single Registration Number: US-MF-000014051
2510 Conway Ave. St. Paul, MN 55144 USA

hereby declare under our sole responsibility that the following CE marked device

Trade Name	3M™ Filtek™ Supreme Flowable Restorative
Intended Purpose	Dental composite resin for anterior and posterior restorations
Reference	**Syringe delivery system:** 6032A1| 6032A2| 6032A3| 6032A3.5| 6032A4| 6032B1| 6032B2| 6032C2| 6032D2| 6032W| 6032XW| 6032OA3| 6032A2-S| 6032A3-S
	Capsule delivery system: 6033A1| 6033A2| 6033A3| 6033A3.5| 6033A4| 6033B1| 6033B2| 6033C2| 6033D2| 6033W| 6033XW| 6033OA3| 6033A2-S
Basic UDI-DI	**Syringe delivery system:** 06082238401020000000029BH
	Capsule delivery system: 06082238401020000000030B2

is classified per rule 8 and 19 of Annex VIII of the Medical Device Regulation (EU) 2017/745, as Class IIa devices in accordance with Annex IX and all other applicable provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning medical devices.

We hereby declare under our sole responsibility that the following CE marked accessories which are intended to be used together with the above medical device

Accessories	Reference	Basic UDI-DI	Rules of Annex VIII	Class
3M™ Filtek™ Flowable Dispensing Tips	3700T 370027T 3740T	06082238401020000000012AY	5	I

are classified according to Annex VIII of the Medical Device Regulation (EU) 2017/745 in accordance with all applicable provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning medical devices.

This declaration is made based on the EU Quality Assurance Certificate G10 117189 0001

Issued by TUV SUD Product Service GmbH (identification no. 0123)

EU Authorized Representative:

EU Representative Address
3M Deutschland GmbH
Health Care Business
Single Registration Number:
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DocuSigned by:
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Suzanne Leung, Ph.D., RAC
Global Regulatory Affairs Director
3M Oral Care Solutions Division

12/16/2022 (St Paul, MN)
Date/Location