3M ESPE
Dental Products

2510 Conway Avenue
St. Paul, MN 55144 USA

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: 34782 Dental Bonding Agent

UMDNS CODE: 10-034 Adhesives

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

Product Family: Dental Adhesives

Product: Adper™ Scotchbond™ Multi-Purpose Adhesive
CE Mark Date: June, 1994

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 13485:2003, 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, 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

Gretchen E. Keenan	Manager 3M ESPE Regulatory Affairs	St.Paul, MN USA	20 Jan 2017
	Title	Location	Date

Revision 17Nov2016

EC DECLARATION OF CONFORMITY

Product Family: Dental Adhesive
Device Description: Non-sterile dental restorative material
EC Product Class (Per Annex IX Rules): Class: IIa Rule: 8
Product:
- Adper Scotchbond Multi-Purpose Adhesive

Item	Catalogue / Order Number
Kits	
Adper™ Scotchbond™ Multi-Purpose Adhesive System • 1 - 8 ml Adper™ Scotchbond™ Multi-Purpose Primer • 1 - 8 ml Adper™ Scotchbond™ Multi-Purpose Adhesive • 2 - 3 ml Scotchbond™ Universal Etchant • 3 color-coded applicator handles • 1 bag (25 each) Etchant dispensing tips • 1 bag (60 each) Applicator brushes • 3 well mix tray • Instructions for Use	7540S
Refills	
8 ml Adper™ Scotchbond™ Multi-Purpose Primer	7542
8 ml Adper™ Scotchbond™ Multi-Purpose Adhesive	7543