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:	Pit and Fissure Sealants	Product(s):	Clinpro Sealant
Device Class:	IIa per Rule V 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
12631	**Clinpro Sealant Introductory Kit, Bottle** • 2 Bottles Sealant (2 x 6 ml) • 1 Bottle Etchant (9 ml) • 2 Brush Handles • 60 Brush Tips • 50 Fiber Tips • 1 Mixing Well • Instructions for Use
12632	**Clinpro Sealant Refill, Bottle** • 1 Bottle Sealant (6 ml) • Instructions for Use
12636	**Clinpro Sealant Introductory Kit, Syringe** • 2 Syringes Sealant (2 x 1.2 ml) • 1 Syringe Etchant Gel (3 ml) • 20 Sealant Dispensing Tips • 25 Etchant Dispensing Tips • Instructions for Use
12637	**Clinpro Sealant Refill, Syringe** • 1 Syringe Sealant (1.2 ml) • 10 Sealant Dispensing Tips • Instructions for Use