



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: Preformed Crowns

Product(s): Protemp™ Crown
Temporization Material

Device Class: IIa per Rule VII 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, PhD., RAC
Regulatory Affairs Director
3M ESPE Dental Products

24 May 2022

Date

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Item Number	Description
Kits	
50600	Protomp Crown Temporization Material - Introductory Kit 42 Temporary Crowns 6 - Molar Upper Large and Upper Small each 6 - Molar Lower Large and Lower Small each 4 - Bicuspid Upper Large and Upper Small each 4 - Bicuspid Lower 3 - Cuspid Large 3 - Cuspid Small - Sizing Tools (2 bags of 10)
50600TK	Protomp Crown Temporization Material – Trial Kit 16 Temporary Crowns 3 - Molar Upper Large and Upper Small each 2 - Molar Lower Large and Lower Small each 2 - Bicuspid Upper Large and Upper Small each 2 - Bicuspid Lower - Sizing Tools (1 bag of 10)
50600SAM	Protomp Crown Temporization Material – Promotional Kit 50600 Kit 50613 Refill
Refills	
50610	Protomp Crown Temporization Material - Molar Upper Large 5 Temporary Crowns – Molar Upper Large 2 Sizing Tools
50611	Protomp Crown Temporization Material - Molar Upper Small 5 Temporary Crowns – Molar Upper Small 2 Sizing Tools
50612	Protomp Crown Temporization Material - Molar Lower Large 5 Temporary Crowns – Molar Lower Large 2 Sizing Tools
50613	Protomp Crown Temporization Material - Molar Lower Small 5 Temporary Crowns – Molar Lower Small 2 Sizing Tools
50614	Protomp Crown Temporization Material – Bicuspid Upper Large 5 Temporary Crowns – Bicuspid Upper Large 2 Sizing Tools
50615	Protomp Crown Temporization Material – Bicuspid Upper Small 5 Temporary Crowns – Bicuspid Upper Small 2 Sizing Tools
50616	Protomp Crown Temporization Material – Bicuspid Lower 5 Temporary Crowns – Bicuspid Lower 2 Sizing Tools
50617	Protomp Crown Temporization Material – Cuspid Large 5 Temporary Crowns – Cuspid Large 2 Sizing Tools
50618	Protomp Crown Temporization Material – Cuspid Small 5 Temporary Crowns – Cuspid Small 2 Sizing Tools