



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:	Glass Ionomers	Product(s):	Ketac™ Cem Plus Ketac™ Cem Plus Automix
Device Class:	IIa per Rule VIII 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

Date

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Item Number	Description
Ketac™ Cem Plus Resin Modified Glass Ionomer Cement	
56930	Ketac Cem Plus Resin Modified Glass Ionomer Cement <ul style="list-style-type: none"> • 2 – 11 g Ketac™ Cem Plus Luting Cement in Clicker™ Dispenser • 1 mixing pad • Instructions for use
56931	Ketac Cem Plus Luting Cement Trial Kit <ul style="list-style-type: none"> • 1 – 11 g Ketac™ Cem Plus Luting Cement in Clicker™ Dispenser • 1 mixing pad • Instructions for use
Ketac™ Cem Plus Automix Resin Modified Glass Ionomer Cement	
3536	Ketac Cem Plus Automix Resin Modified Glass Ionomer Cement <ul style="list-style-type: none"> • 3 – 8.5 g Ketac Cem Plus Automix Dispenser • 3 – 12 count Ketac Cem Plus Automix Mixing tips • Instructions for use
3536TK	Ketac Cem Plus Automix Resin Modified Glass Ionomer Cement <ul style="list-style-type: none"> • 1 – 8.5 g Ketac Cem Plus Automix Dispenser • 1 – 12 count Ketac Cem Plus Automix Mixing tips • Instructions for use
3536SK	Ketac Cem Plus Automix Resin Modified Glass Ionomer Cement <ul style="list-style-type: none"> • 1 – 4.25 g Ketac Cem Plus Automix Dispenser • 3 – 6 count Ketac Cem Plus Automix Mixing tips • Instructions for use