



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:	Resin Based Materials	Product(s):	RelyX™ Veneer Cement RelyX™ Try-In Paste
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
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Suzanne Leung, PhD., RAC
Regulatory Affairs Director
3M ESPE Dental Products

Date

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Item Number	Description
Kits	
7616	RelyX Veneer Cement Kit <ul style="list-style-type: none"> • 5 x 3 g syringes of RelyX Veneer Cement (shades A1, A3, White/Opaque (WO), Translucent (TR) and B0.5) • 5 x 2 g syringes of RelyX Try-in Paste (shades A1, A3, White/Opaque, Translucent and B0.5) • 1 x 5ml Scotchbond Universal Adhesive • 1 x 3 ml syringe Scotchbond Universal Etchant • 25 x Etchant dispensing tips • 48 Mixing wells • 50 microbrushes • Instructions for Use
7616TK	RelyX Veneer Cement Kit <ul style="list-style-type: none"> • 1 x 3 g syringes of RelyX Veneer Cement (translucent shade) • 1 x 2 g syringes of RelyX Try-in Paste (translucent shade) • 1 x 3 ml syringe Scotchbond Universal Etchant • 20 x Scotchbond Universal L-Pops • 25 x Etchant dispensing tips • Instructions for Use
Refills	
8714A1	RelyX Veneer Cement A1 Shade
8714A3	RelyX Veneer Cement A3 Shade
8714A5	RelyX Veneer Cement A5 Shade
8714WO	RelyX Veneer Cement WO Shade
8714TR	RelyX Veneer Cement TR Shade
8714B0.5	RelyX Veneer Cement B0.5 Shade
7614A1T	RelyX Try-in Paste A1 Shade
7614A3T	RelyX Try-in Paste A3 Shade
7614A5T	RelyX Try-in Paste A5 Shade
7614WOT	RelyX Try-in Paste WO Shade
7614TRT	RelyX Try-in Paste TR Shade
7614B0.5T	RelyX Try-in Paste B0.5 Shade