

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: 35870 Resin Composite,  
Dental Cement

**Manufacturing Facility:**

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

Product Family: Resin Based Materials

Product: RelyX™ Veneer Cement  
RelyX™ Try-In Paste

EC Product Class: IIa  
Rule: 8

Per Annex IX of the Medical Device Directive

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## 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 13485:2016, 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

  
Suzanne Leung

Manager  
3M ESPE  
Regulatory Affairs  
Title

St. Paul, MN USA  
Location

06 Sep 2019  
Date

## EC DECLARATION OF CONFORMITY

**Product Family:**

**Resin Based Materials**

**Device Description:**

Non-Sterile Dental Restorative Materials

**EC Product Class (Per Annex IX Rules):**

Class: IIa Rule: 8

**Product:**

- ◆ RelyX™ Veneer Cement
- ◆ RelyX™ Try-In Paste

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