



## 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: MD 0402 Dental Materials

Product(s): Lava™ Ultimate CAD/CAM  
Restorative for CEREC®

Device Class: IIa per Rule VIII in Annex IX  
of 93/42/EEC as amended by  
2007/47/EC

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## 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
3312BL-LT	Lava Ultimate CAD/CAM Restorative for CEREC, 5 blocks; size 12; shade Bleach
3312A1-HT	Lava Ultimate CAD/CAM Restorative for CEREC, 5 blocks; size 12; shade A1 – HT
3312A1-LT	Lava Ultimate CAD/CAM Restorative for CEREC, 5 blocks; size 12; shade A1 – LT
3312A2-HT	Lava Ultimate CAD/CAM Restorative for CEREC, 5 blocks; size 12; shade A2 – HT
3312A2-LT	Lava Ultimate CAD/CAM Restorative for CEREC, 5 blocks; size 12; shade A2 – LT
3312A3-HT	Lava Ultimate CAD/CAM Restorative for CEREC, 5 blocks; size 12; shade A3 – HT
3312A3-LT	Lava Ultimate CAD/CAM Restorative for CEREC, 5 blocks; size 12; shade A3 – LT
3312A3.5-LT	Lava Ultimate CAD/CAM Restorative for CEREC, 5 blocks; size 12; shade A3.5 – LT
3312B1-HT	Lava Ultimate CAD/CAM Restorative for CEREC, 5 blocks; size 12; shade B1 – HT
3312B1-LT	Lava Ultimate CAD/CAM Restorative for CEREC, 5 blocks; size 12; shade B1 – LT
3312C2-LT	Lava Ultimate CAD/CAM Restorative for CEREC, 5 blocks; size 12; shade C2 – LT
3312D2-LT	Lava Ultimate CAD/CAM Restorative for CEREC, 5 blocks; size 12; shade D2 – LT
3314BL-LT	Lava Ultimate CAD/CAM Restorative for CEREC, 5 blocks, size 14L, shade Bleach
3314A1-HT	Lava Ultimate CAD/CAM Restorative for CEREC, 5 blocks, size 14L, shade A1-HT
3314A1-LT	Lava Ultimate CAD/CAM Restorative for CEREC, 5 blocks, size 14L, shade A1-LT
3314A2-HT	Lava Ultimate CAD/CAM Restorative for CEREC, 5 blocks, size 14L, shade A2-HT
3314A2-LT	Lava Ultimate CAD/CAM Restorative for CEREC, 5 blocks; size 14L; shade A2 – LT
3314A3-HT	Lava Ultimate CAD/CAM Restorative for CEREC, 5 blocks; size 14L; shade A3 – HT
3314A3-LT	Lava Ultimate CAD/CAM Restorative for CEREC, 5 blocks; size 14L; shade A3 – LT
3314A3.5-LT	Lava Ultimate CAD/CAM Restorative for CEREC, 5 blocks; size 14L; shade A3.5 – LT
3314B1-HT	Lava Ultimate CAD/CAM Restorative for CEREC, 5 blocks; size 14L; shade B1 – HT
3314B1-LT	Lava Ultimate CAD/CAM Restorative for CEREC, 5 blocks; size 14L; shade B1 – LT