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CE 0123

Declaration of conformity

Manufacturer Address	Ivoclar Vivadent AG Bendererstrasse 2 9494 Schaan Liechtenstein
Product	**Tetric EvoCeram®** **Ceramic Repair System Kit**
Type of material	Lightcuring resin-based dental restorative material
Product category	Filling materials
Classification	Medical Device Class IIa

We hereby declare under our exclusive responsibility that the above mentioned products meet the provisions of the following EC Council Directives and its implementation in national law. All supporting documentation is retained on the premises of the manufacturer and the notified body.

Directives	Medical Device Directive 93/42/EEC, Annex II. 3
Notified Body Address	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 München Deutschland
Place, Valid from	Schaan, 2016-02-01 Replaces version of: 2015-08-21
Valid until	2021-01-31

Signature		
Name Position	Dr. Thomas Hirt CTO	Dipl. Ing. Patrik Oehri Director CQM and Regulatory Sicherheitsbeauftragter (Product Safety Officer)
Date	2016-02-01	2016-02-01

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Attachment to Declaration of conformity

Product **Tetric EvoCeram®**
Ceramic Repair System Kit

Dated 2016-02-01

638503	Tetric EvoCeram Sample Pack 3x0.2g A2 US	590325	Tetric EvoCeram Ref. 1x3 g B2 Dentin
590290	Tetric EvoCeram Assortment 8x3 g	590326	Tetric EvoCeram Ref. 1x3 g T
590291	Tetric EvoCeram Assortment 40x0.2 g	590327	Tetric EvoCeram Ref. 1x3 g Bleach XL
590293	Tetric EvoCeram Ref. 3x3 g A1	590328	Tetric EvoCeram Ref. 1x3 g Bleach L
590294	Tetric EvoCeram Ref. 3x3 g A2	590329	Tetric EvoCeram Ref. 1x3 g Bleach I
590295	Tetric EvoCeram Ref. 3x3 g A3	590330	Tetric EvoCeram Ref. 1x3 g Bleach M
590296	Tetric EvoCeram Ref. 3x3 g A3.5	590331	Tetric EvoCeram Ref. 20x0.2 g A1
590297	Tetric EvoCeram Ref. 3x3 g A4	590332	Tetric EvoCeram Ref. 20x0.2 g A2
590298	Tetric EvoCeram Ref. 3x3 g B2	590333	Tetric EvoCeram Ref. 20x0.2 g A3
590299	Tetric EvoCeram Ref. 3x3 g B3	590334	Tetric EvoCeram Ref. 20x0.2 g A3.5
590300	Tetric EvoCeram Ref. 3x3 g C1	590335	Tetric EvoCeram Ref. 20x0.2 g A4
590301	Tetric EvoCeram Ref. 3x3 g C2	590336	Tetric EvoCeram Ref. 20x0.2 g B2
590302	Tetric EvoCeram Ref. 3x3 g C3	590337	Tetric EvoCeram Ref. 20x0.2 g B3
590303	Tetric EvoCeram Ref. 3x3 g D3	590338	Tetric EvoCeram Ref. 20x0.2 g C1
590304	Tetric EvoCeram Ref. 3x3 g A3.5 Dentin	590339	Tetric EvoCeram Ref. 20x0.2 g C2
590305	Tetric EvoCeram Ref. 3x3 g A4 Dentin	590340	Tetric EvoCeram Ref. 20x0.2 g C3
590306	Tetric EvoCeram Ref. 3x3 g B2 Dentin	590341	Tetric EvoCeram Ref. 20x0.2 g D3
590307	Tetric EvoCeram Ref. 3x3 g T	590342	Tetric EvoCeram Ref. 20x0.2 g A3.5 Den.
590308	Tetric EvoCeram Ref. 3x3 g Bleach XL	590343	Tetric EvoCeram Ref. 20x0.2 g A4 Dentin
590309	Tetric EvoCeram Ref. 3x3 g Bleach L	590344	Tetric EvoCeram Ref. 20x0.2 g B2 Dentin
590310	Tetric EvoCeram Ref. 3x3 g Bleach I	590345	Tetric EvoCeram Ref. 20x0.2 g T
590311	Tetric EvoCeram Ref. 3x3 g Bleach M	590346	Tetric EvoCeram Ref. 20x0.2 g Bleach XL
590312	Tetric EvoCeram Ref. 1x3g A1	590347	Tetric EvoCeram Ref. 20x0.2 g Bleach L
590313	Tetric EvoCeram Ref. 1x3g A2	590348	Tetric EvoCeram Ref. 20x0.2 g Bleach I
590314	Tetric EvoCeram Ref. 1x3g A3	590349	Tetric EvoCeram Ref. 20x0.2 g Bleach M
590315	Tetric EvoCeram Ref. 1x3g A3.5	591957	Tetric EvoCeram Test Pack A3 3x0.2 g
590316	Tetric EvoCeram Ref. 1x3g A4	592017	Tetric EvoCeram Test Pack A3 1x1 g
590317	Tetric EvoCeram Ref. 1x3g B2	594774	Tetric EvoCeram Test Pack A2 3x0.2 g
590318	Tetric EvoCeram Ref. 1x3g B3	628838	Ceramic Repair System Kit
590319	Tetric EvoCeram Ref. 1x3 g C1	637247	Tetric EvoCeram JumboPack 5A2/5A3 3g
590320	Tetric EvoCeram Ref. 1x3 g C2	637255	Tetric EvoCeram JumboPack 75A2/75A3 0.2g
590321	Tetric EvoCeram Ref. 1x3 g C3	637354	Tetric EvoCeram Ref. 20x0.2 g B1
590322	Tetric EvoCeram Ref. 1x3 g D3	637355	Tetric EvoCeram Ref. 20x0.2 g D2
590323	Tetric EvoCeram Ref. 1x3 g A3.5 Dentin	637356	Tetric EvoCeram Ref. 20x0.2 g A2 Dentin
590324	Tetric EvoCeram Ref. 1x3 g A4 Dentin	637547	Tetric EvoCeram Ref. 1x3g B1

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637548 Tetric EvoCeram Ref. 1x3g D2
637549 Tetric EvoCeram Ref. 1x3g A2 Dentin
637734 Tetric EvoCeram Ref. 3x3g B1
637735 Tetric EvoCeram Ref. 3x3g D2
637736 Tetric EvoCeram Ref. 3x3g A2 Dentin
637800 Tetric EvoCeram Promo Pack 2x1g A2/A3
637801 Tetric EvoCeram Promo Pack 10x0.2g A2/A3
638378 Tetric EvoCeram Assortment 8x3g US
638381 Tetric EvoCeram Assortment 40x0.2g US
638382 Tetric EvoCeram Sample Pack 3x0.2g A2
638387 TEC Sample P. A2 1x1g/AOF/OptraPol
638388 TEC Sample P. A2 3x0,2g/AOF/OptraPol
638389 Tetric EvoCeram Sample Pack 1x1g A2
642040 Tetric EvoCeram Jumbo Ref. 150x0.2g A2
642041 Tetric EvoCeram Jumbo Ref. 150x0.2g A3
642042 Tetric EvoCeram Jumbo Ref. 10x3 g A2
642043 Tetric EvoCeram Jumbo Ref. 10x3 g A3
681133 Tetric EvoCeram Sample Pack 1x1g A3
681135 Tetric EvoCeram Sample Pack 3x0.2g A3

Place, Valid from	Schaan, 2016-04-11 Replaces version of: 2016-02-01	
Signature		
Name	Dr. Marion Wanner	Sandra Cakebread
Position	Scientific Service, R&D	Regulatory Affairs, R&D
Date	2016-04-11	2016-04-11

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