

EU Declaration of Conformity for Class_Ila_349393020

Document Information (OTCS)	
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Signatures	
Author(s)	The signatures of all involved signatories are added on the last page of this document.
Reviewer(s)	
Approver(s)	

EU Declaration of Conformity according to Medical Device Regulation MDR 2017/745 Annex IV

We hereby declare that this EU Declaration of Conformity is issued under the sole responsibility of the manufacturer and the below mentioned products meet the provisions of the EU Regulation above. All supporting documentation is retained on the premises of the manufacturer and the Notified Body.

Product(s)	Tetric EvoCeram
Basic-UDI-DI	76152082AFILL004JG

Legal manufacturer		
	Ivoclar Vivadent AG Bendererstrasse 2 9494 Schaan/Liechtenstein www.ivoclar.com	Phone +423 / 235 35 35, Fax +423 / 235 33 60 www.ivoclar.com Legal Form: Joint Stock Company Corporate Headquarters: 9494 Schaan Registration No.: FL-0001.001.595-7 VAT No.: 50639

EU Declaration of Conformity Information	
SRN (Legal Manufacturer)	LI-MF-000000522
Intended Purpose	Direct restoration of anterior and posterior teeth
Category (MDCG 2019-14)	MDN 1103 Non-active dental implants and dental materials
EMDN Code + term	Q01010103 Dental Conservation Composites
MDS Code	MDS 1007
MDT Code	MDT 2006 MDT 2011
EU Classification	☒ Medical Device ☐ Accessory for Medical Device
EU Risk Class (MDR Annex VIII)	Class IIa CE 0123
Conformity Assessment Procedure (MDR Annex IX)	☒ Quality Management System ☐ Assessment of the Technical Documentation
Notified Body Address	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 Munich Germany
EC Certificate No.	G10 043306 0270 Rev. 01
Valid until	2026-05-04

Attachment to EU Declaration of Conformity

Article No.	Description	MDR Classification (EU)	Rule MDR (EU)
590293WW	Tetric EvoCeram Refill 3x3g A1	Ila	8
590294WW	Tetric EvoCeram Refill 3x3g A2	Ila	8
590295WW	Tetric EvoCeram Refill 3x3g A3	Ila	8
590296WW	Tetric EvoCeram Refill 3x3g A3.5	Ila	8
590297WW	Tetric EvoCeram Refill 3x3g A4	Ila	8
590298WW	Tetric EvoCeram Refill 3x3g B2	Ila	8
590301WW	Tetric EvoCeram Refill 3x3g C2	Ila	8
590302WW	Tetric EvoCeram Refill 3x3g C3	Ila	8
590303WW	Tetric EvoCeram Refill 3x3g D3	Ila	8
590304WW	Tetric EvoCeram Refill 3x3g A3.5 Dentin	Ila	8
590307WW	Tetric EvoCeram Refill 3x3g T	Ila	8
590308WW	Tetric EvoCeram Refill 3x3g Bleach XL	Ila	8
590312US	Tetric EvoCeram Refill 1x3g A1	Ila	8
590312WW	Tetric EvoCeram Refill 1x3g A1	Ila	8
590313US	Tetric EvoCeram Refill 1x3g A2	Ila	8
590313WW	Tetric EvoCeram Refill 1x3g A2	Ila	8
590314US	Tetric EvoCeram Refill 1x3g A3	Ila	8
590314WW	Tetric EvoCeram Refill 1x3g A3	Ila	8
590315US	Tetric EvoCeram Refill 1x3g A3.5	Ila	8
590315WW	Tetric EvoCeram Refill 1x3g A3.5	Ila	8
590316WW	Tetric EvoCeram Refill 1x3g A4	Ila	8
590317WW	Tetric EvoCeram Refill 1x3g B2	Ila	8
590318WW	Tetric EvoCeram Refill 1x3g B3	Ila	8
590319WW	Tetric EvoCeram Refill 1x3g C1	Ila	8
590320WW	Tetric EvoCeram Refill 1x3g C2	Ila	8
590321WW	Tetric EvoCeram Refill 1x3g C3	Ila	8
590322WW	Tetric EvoCeram Refill 1x3g D3	Ila	8
590323WW	Tetric EvoCeram Refill 1x3g A3.5 Dentin	Ila	8
590324WW	Tetric EvoCeram Refill 1x3g A4 Dentin	Ila	8
590325WW	Tetric EvoCeram Refill 1x3g B2 Dentin	Ila	8
590326US	Tetric EvoCeram Refill 1x3g T	Ila	8
590326WW	Tetric EvoCeram Refill 1x3g T	Ila	8
590327WW	Tetric EvoCeram Refill 1x3g Bleach XL	Ila	8
590328WW	Tetric EvoCeram Refill 1x3g Bleach L	Ila	8
590329WW	Tetric EvoCeram Refill 1x3g Bleach I	Ila	8
590330WW	Tetric EvoCeram Refill 1x3g Bleach M	Ila	8
590331US	Tetric EvoCeram Ref. 20x0.2g A1	Ila	8
590331WW	Tetric EvoCeram Ref. 20x0.2g A1	Ila	8
590332US	Tetric EvoCeram Ref. 20x0.2g A2	Ila	8
590332WW	Tetric EvoCeram Ref. 20x0.2g A2	Ila	8
590333US	Tetric EvoCeram Ref. 20x0.2g A3	Ila	8
590333WW	Tetric EvoCeram Ref. 20x0.2g A3	Ila	8
590334US	Tetric EvoCeram Ref. 20x0.2g A3.5	Ila	8
590334WW	Tetric EvoCeram Ref. 20x0.2g A3.5	Ila	8
590335US	Tetric EvoCeram Ref. 20x0.2g A4	Ila	8
590335WW	Tetric EvoCeram Ref. 20x0.2g A4	Ila	8

590336WW	Tetric EvoCeram Ref. 20x0.2g B2	Ila	8
590337WW	Tetric EvoCeram Ref. 20x0.2g B3	Ila	8
590338WW	Tetric EvoCeram Ref. 20x0.2g C1	Ila	8
590339WW	Tetric EvoCeram Ref. 20x0.2g C2	Ila	8
590340WW	Tetric EvoCeram Ref. 20x0.2g C3	Ila	8
590341WW	Tetric EvoCeram Ref. 20x0.2g D3	Ila	8
590342WW	Tetric EvoCeram Ref. 20x0.2g A3.5 Dent.	Ila	8
590343WW	Tetric EvoCeram Ref. 20x0.2g A4 Dentin	Ila	8
590344WW	Tetric EvoCeram Ref. 20x0.2g B2 Dentin	Ila	8
590345US	Tetric EvoCeram Ref. 20x0.2g T	Ila	8
590345WW	Tetric EvoCeram Ref. 20x0.2g T	Ila	8
590346WW	Tetric EvoCeram Ref. 20x0.2g Bleach XL	Ila	8
590347WW	Tetric EvoCeram Ref. 20x0.2g Bleach L	Ila	8
590348WW	Tetric EvoCeram Ref. 20x0.2g Bleach I	Ila	8
590349WW	Tetric EvoCeram Ref. 20x0.2g Bleach M	Ila	8
637354US	Tetric EvoCeram Ref. 20x0.2g B1	Ila	8
637354WW	Tetric EvoCeram Ref. 20x0.2g B1	Ila	8
637355WW	Tetric EvoCeram Ref. 20x0.2g D2	Ila	8
637356US	Tetric EvoCeram Ref. 20x0.2g A2 Dentin	Ila	8
637356WW	Tetric EvoCeram Ref. 20x0.2g A2 Dentin	Ila	8
637547WW	Tetric EvoCeram Refill 1x3g B1	Ila	8
637548WW	Tetric EvoCeram Refill 1x3g D2	Ila	8
637549WW	Tetric EvoCeram Refill 1x3g A2 Dentin	Ila	8
637736WW	Tetric EvoCeram Refill 3x3g A2 Dentin	Ila	8
642040WW	Tetric EvoCeram Jumbo Ref. 150x0.2g A2	Ila	8
642041WW	Tetric EvoCeram Jumbo Ref. 150x0.2g A3	Ila	8
642042WW	Tetric EvoCeram Jumbo Ref. 10x3g A2	Ila	8
642043WW	Tetric EvoCeram Jumbo Ref. 10x3g A3	Ila	8
705157	Tetric EvoCeram Invisalign Kit 3x0.2g T	Ila	8
762518WW	Tetric EvoCeram Aligner Ref 20x0.2g T	Ila	8
762519WW	Tetric EvoCeram Aligner Ref 1x3g T	Ila	8

Revision History			
Version	Date	Author	Remark
1.0	2024-03-07	R. Tsoleva	First MDR Version
2.0	2025-02-26	R. Ritter	New TEFO for e-signature Update Attachment acc. Design Review Change OTCS102281003

Signing Page

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Document Approval (OTCS)

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