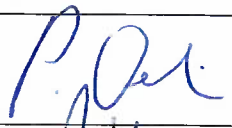
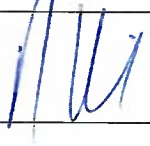
EU Declaration of Conformity according to Medical Device Regulation MDR 2017/745 Annex IV

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	Tetric EvoCeram
Basic-UDI-DI	76152082AFILL004JG
Document-ID	OTCS8816712
Document Version	1.0

Legal manufacturer		
ivoclar	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	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 Risk Classification (MDR Annex VIII)	Medical Device 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 München Deutschland
EC Certificate No.	G10 043306 0270 Rev. 01
Valid until	2026-05-04

Document Control			
Name	**Place of issue**	**Date of issue**	**Signature**
Approver (PRRC): Patrik Oehri	Schaan, LI	05.03.2024	
Approver (CTO): Dr. Thomas Hirt	Schaan, LI	05.03.2024	

Revision History			
Version	**Date**	**Author**	**Remark**
1.0	2024-03-04	Ruska Tsolova	First MDR Version

ivoclar

Attachment to EU Declaration of Conformity (MDR) of
TETRIC EVOCERAM

Article No.	Description	MDR Classification (EU)	Rule MDR (EU)
590293WW	Tetric EvoCeram Refill 3x3g A1	CLASS IIA	8
590294WW	Tetric EvoCeram Refill 3x3g A2	CLASS IIA	8
590295WW	Tetric EvoCeram Refill 3x3g A3	CLASS IIA	8
590296WW	Tetric EvoCeram Refill 3x3g A3.5	CLASS IIA	8
590297WW	Tetric EvoCeram Refill 3x3g A4	CLASS IIA	8
590298WW	Tetric EvoCeram Refill 3x3g B2	CLASS IIA	8
590301WW	Tetric EvoCeram Refill 3x3g C2	CLASS IIA	8
590302WW	Tetric EvoCeram Refill 3x3g C3	CLASS IIA	8
590303WW	Tetric EvoCeram Refill 3x3g D3	CLASS IIA	8
590304WW	Tetric EvoCeram Refill 3x3g A3.5 Dentin	CLASS IIA	8
590307WW	Tetric EvoCeram Refill 3x3g T	CLASS IIA	8
590308WW	Tetric EvoCeram Refill 3x3g Bleach XL	CLASS IIA	8
590312US	Tetric EvoCeram Refill 1x3g A1	CLASS IIA	8
590312WW	Tetric EvoCeram Refill 1x3g A1	CLASS IIA	8
590313US	Tetric EvoCeram Refill 1x3g A2	CLASS IIA	8
590313WW	Tetric EvoCeram Refill 1x3g A2	CLASS IIA	8
590314US	Tetric EvoCeram Refill 1x3g A3	CLASS IIA	8
590314WW	Tetric EvoCeram Refill 1x3g A3	CLASS IIA	8
590315US	Tetric EvoCeram Refill 1x3g A3.5	CLASS IIA	8
590315WW	Tetric EvoCeram Refill 1x3g A3.5	CLASS IIA	8
590316WW	Tetric EvoCeram Refill 1x3g A4	CLASS IIA	8
590317WW	Tetric EvoCeram Refill 1x3g B2	CLASS IIA	8
590318WW	Tetric EvoCeram Refill 1x3g B3	CLASS IIA	8
590319WW	Tetric EvoCeram Refill 1x3g C1	CLASS IIA	8
590320WW	Tetric EvoCeram Refill 1x3g C2	CLASS IIA	8
590321WW	Tetric EvoCeram Refill 1x3g C3	CLASS IIA	8
590322WW	Tetric EvoCeram Refill 1x3g D3	CLASS IIA	8
590323WW	Tetric EvoCeram Refill 1x3g A3.5 Dentin	CLASS IIA	8
590324WW	Tetric EvoCeram Refill 1x3g A4 Dentin	CLASS IIA	8

The suffix of the article number (e.g. "AN", "EN", "AL", "WW") is only used for in-house reference and relates to the language version and/or electrical plug of the product. The suffix does not belong to the official article number.

ivoclar

Attachment to EU Declaration of Conformity (MDR) of
TETRIC EVOCERAM

Article No.	Description	MDR Classification (EU)	Rule MDR (EU)
590325WW	Tetric EvoCeram Refill 1x3g B2 Dentin	CLASS IIA	8
590326US	Tetric EvoCeram Refill 1x3g T	CLASS IIA	8
590326WW	Tetric EvoCeram Refill 1x3g T	CLASS IIA	8
590327WW	Tetric EvoCeram Refill 1x3g Bleach XL	CLASS IIA	8
590328WW	Tetric EvoCeram Refill 1x3g Bleach L	CLASS IIA	8
590329WW	Tetric EvoCeram Refill 1x3g Bleach I	CLASS IIA	8
590330WW	Tetric EvoCeram Refill 1x3g Bleach M	CLASS IIA	8
590331US	Tetric EvoCeram Ref. 20x0.2g A1	CLASS IIA	8
590331WW	Tetric EvoCeram Ref. 20x0.2g A1	CLASS IIA	8
590332US	Tetric EvoCeram Ref. 20x0.2g A2	CLASS IIA	8
590332WW	Tetric EvoCeram Ref. 20x0.2g A2	CLASS IIA	8
590333US	Tetric EvoCeram Ref. 20x0.2g A3	CLASS IIA	8
590333WW	Tetric EvoCeram Ref. 20x0.2g A3	CLASS IIA	8
590334US	Tetric EvoCeram Ref. 20x0.2g A3.5	CLASS IIA	8
590334WW	Tetric EvoCeram Ref. 20x0.2g A3.5	CLASS IIA	8
590335US	Tetric EvoCeram Ref. 20x0.2g A4	CLASS IIA	8
590335WW	Tetric EvoCeram Ref. 20x0.2g A4	CLASS IIA	8
590336WW	Tetric EvoCeram Ref. 20x0.2g B2	CLASS IIA	8
590337WW	Tetric EvoCeram Ref. 20x0.2g B3	CLASS IIA	8
590338WW	Tetric EvoCeram Ref. 20x0.2g C1	CLASS IIA	8
590339WW	Tetric EvoCeram Ref. 20x0.2g C2	CLASS IIA	8
590340WW	Tetric EvoCeram Ref. 20x0.2g C3	CLASS IIA	8
590341WW	Tetric EvoCeram Ref. 20x0.2g D3	CLASS IIA	8
590342WW	Tetric EvoCeram Ref. 20x0.2g A3.5 Dent.	CLASS IIA	8
590343WW	Tetric EvoCeram Ref. 20x0.2g A4 Dentin	CLASS IIA	8
590344WW	Tetric EvoCeram Ref. 20x0.2g B2 Dentin	CLASS IIA	8
590345US	Tetric EvoCeram Ref. 20x0.2g T	CLASS IIA	8
590345WW	Tetric EvoCeram Ref. 20x0.2g T	CLASS IIA	8
590346WW	Tetric EvoCeram Ref. 20x0.2g Bleach XL	CLASS IIA	8

The suffix of the article number (e.g. "AN", "EN", "AL", "WW") is only used for in-house reference and relates to the language version and/or electrical plug of the product. The suffix does not belong to the official article number.

ivoclar

Attachment to EU Declaration of Conformity (MDR) of
TETRIC EVOCERAM

Article No.	Description	MDR Classification (EU)	Rule MDR (EU)
590347WW	Tetric EvoCeram Ref. 20x0.2g Bleach L	CLASS IIA	8
590348WW	Tetric EvoCeram Ref. 20x0.2g Bleach I	CLASS IIA	8
590349WW	Tetric EvoCeram Ref. 20x0.2g Bleach M	CLASS IIA	8
637354US	Tetric EvoCeram Ref. 20x0.2g B1	CLASS IIA	8
637354WW	Tetric EvoCeram Ref. 20x0.2g B1	CLASS IIA	8
637355WW	Tetric EvoCeram Ref. 20x0.2g D2	CLASS IIA	8
637356US	Tetric EvoCeram Ref. 20x0.2g A2 Dentin	CLASS IIA	8
637356WW	Tetric EvoCeram Ref. 20x0.2g A2 Dentin	CLASS IIA	8
637547WW	Tetric EvoCeram Refill 1x3g B1	CLASS IIA	8
637548WW	Tetric EvoCeram Refill 1x3g D2	CLASS IIA	8
637549WW	Tetric EvoCeram Refill 1x3g A2 Dentin	CLASS IIA	8
637736WW	Tetric EvoCeram Refill 3x3g A2 Dentin	CLASS IIA	8
642040WW	Tetric EvoCeram Jumbo Ref. 150x0.2g A2	CLASS IIA	8
642041WW	Tetric EvoCeram Jumbo Ref. 150x0.2g A3	CLASS IIA	8
642042WW	Tetric EvoCeram Jumbo Ref. 10x3g A2	CLASS IIA	8
642043WW	Tetric EvoCeram Jumbo Ref. 10x3g A3	CLASS IIA	8
762518WW	Tetric EvoCeram Aligner Ref 20x0.2g T	CLASS IIA	8
762519WW	Tetric EvoCeram Aligner Ref 1x3g T	CLASS IIA	8

Schaan, 06.03.2024

(this document is valid without signature)

The suffix of the article number (e.g. "AN", "EN", "AL", "WW") is only used for in-house reference and relates to the language version and/or electrical plug of the product. The suffix does not belong to the official article number.