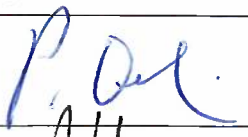
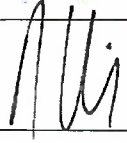
EU Declaration of Conformity according to Medical Device Regulation MDR 2017/745 Annex IV

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 PowerFill**
Basic-UDI-DI	76152082AFILL001JA
Document-ID	OTCS5960000
Document Version	7.0

Legal manufacturer		
ivoclar	Ivoclar Vivadent AG Benderersstrasse 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 restorations of posterior teeth
Category (MDCG 2019-14)	MDN 1103 Non-active dental implants and dental materials
EMDN Code + term	Q01010103 Dental Conversaton 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	08.01.2024	
Approver (CTO): Dr. Thomas Hirt	Schaan, LI	11.01.2024	

Revision History			
Version	**Date**	**Author**	**Remark**
1.0	2022-02-28	R. Ritter	First MDR Version
2.0	2022-05-03	R. Ritter	GSPR updated (2022-05-26)
3.0	2022-06-15	E. Vogt	GSPR updated
4.0	2023-03-13	R. Ritter	GSPR updated (APM107838)
5.0	2023-09-21	R. Ritter	GSPR updated (APM109407, AMP109531)
6.0	2023-10-09	E. Vogt	GSPR updated (APM108714)
7.0	2024-01-03	R. Tsolova	GSPR updated (AMP107709)

ivoclar

Attachment to EU Declaration of Conformity (MDR) of

TETRIC POWERFILL

Article No.	Description	MDR Classification (EU)	Rule MDR (EU)
668076WW	Tetric PowerFill 20x0.2g IVB	CLASS IIA	8
668077WW	Tetric PowerFill 20x0.2g IVW	CLASS IIA	8
668081WW	Tetric PowerFill Test Pack 3x0.2g IVA	CLASS IIA	8
668083WW	Tetric PowerFill Ref. 1x3g IVA	CLASS IIA	8
668084WW	Tetric PowerFill Ref. 1x3g IVB	CLASS IIA	8
668107WW	Tetric PowerFill 20x0.2g IVA	CLASS IIA	8
668115WW	Tetric PowerFill Ref. 1x3g IVW	CLASS IIA	8
668117WW	Tetric PowerFill Ref. 3x3g IVA	CLASS IIA	8
668122WW	Tetric PowerFill Test Pack 1x1g IVA	CLASS IIA	8
759145WW	Tetric PowerFill Refill Syringe	CLASS IIA	8
759197WW	Tetric PowerFill Refill Cavifil 20	CLASS IIA	8
760218WW	Tetric PowerFill Refill Cavifil 10	CLASS IIA	8

Schaan, 13.02.2024

(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.