

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 EvoFlow
Basic-UDI-DI	76152082AFILL005JJ
Document-ID	OTCS6490189
Document Version	1.0

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	LI-MF-000000522
Intended Purpose	Direct restorations 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  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	26.10.2023	
Approver (CTO): Dr. Thomas Hirt	Schaan, LI	26.10.2023	

Revision History			
Version	Date	Author	Remark
1.0	2023-10-27	R. Ritter	First MDR Version

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

Article No.	Description	MDR Classification (EU)	Rule MDR (EU)
595953US	Tetric EvoFlow Refill 1x2g A1	CLASS IIA	8
595953WW	Tetric EvoFlow Refill 1x2g A1	CLASS IIA	8
595954US	Tetric EvoFlow Refill 1x2g A2	CLASS IIA	8
595954WW	Tetric EvoFlow Refill 1x2g A2	CLASS IIA	8
595955US	Tetric EvoFlow Refill 1x2g A3	CLASS IIA	8
595955WW	Tetric EvoFlow Refill 1x2g A3	CLASS IIA	8
595956WW	Tetric EvoFlow Refill 1x2g A3.5	CLASS IIA	8
595957WW	Tetric EvoFlow Refill 1x2g B3	CLASS IIA	8
595978WW	Tetric EvoFlow Refill 1x2g A4	CLASS IIA	8
595979US	Tetric EvoFlow Refill 1x2g T	CLASS IIA	8
595979WW	Tetric EvoFlow Refill 1x2g T	CLASS IIA	8
595980WW	Tetric EvoFlow Refill 1x2g A3.5 Dentin	CLASS IIA	8
595981WW	Tetric EvoFlow Refill 1x2g Bleach XL	CLASS IIA	8
595982WW	Tetric EvoFlow Refill 1x2g Bleach L	CLASS IIA	8
595984WW	Tetric EvoFlow Refill 1x2g Bleach M	CLASS IIA	8
595987US	Tetric EvoFlow Refill 20x0.2g A1	CLASS IIA	8
595987WW	Tetric EvoFlow Refill 20x0.2g A1	CLASS IIA	8
595988US	Tetric EvoFlow Refill 20x0.2g A2	CLASS IIA	8
595988WW	Tetric EvoFlow Refill 20x0.2g A2	CLASS IIA	8
595989US	Tetric EvoFlow Refill 20x0.2g A3	CLASS IIA	8
595989WW	Tetric EvoFlow Refill 20x0.2g A3	CLASS IIA	8
595990WW	Tetric EvoFlow Refill 20x0.2g A3.5	CLASS IIA	8
595991WW	Tetric EvoFlow Refill 20x0.2g B3	CLASS IIA	8
595992WW	Tetric EvoFlow Refill 20x0.2g A4	CLASS IIA	8
595993US	Tetric EvoFlow Refill 20x0.2g T	CLASS IIA	8
595993WW	Tetric EvoFlow Refill 20x0.2g T	CLASS IIA	8
595994WW	Tetric EvoFlow Ref. 20x0.2g A3.5 Dentin	CLASS IIA	8
595995WW	Tetric EvoFlow Refill 20x0.2g Bleach XL	CLASS IIA	8
595996WW	Tetric EvoFlow Refill 20x0.2g Bleach L	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.

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

Article No.	Description	MDR Classification (EU)	Rule MDR (EU)
596008WW	Tetric EvoFlow Refill 20x0.2g Bleach M	CLASS IIA	8
641348WW	Tetric EvoFlow Refill 20x0.2g B1	CLASS IIA	8
641349WW	Tetric EvoFlow Refill 20x0.2g A2 Dentin	CLASS IIA	8
641350WW	Tetric EvoFlow Refill 20x0.2g B2 Dentin	CLASS IIA	8
641358WW	Tetric EvoFlow Refill 1x2g B1	CLASS IIA	8
641360WW	Tetric EvoFlow Refill 1x2g A2 Dentin	CLASS IIA	8
641361WW	Tetric EvoFlow Refill 1x2g B2 Dentin	CLASS IIA	8
700713WW	Tetric EvoFlow Test Pack 1x1.3g A2	CLASS IIA	8
700714WW	Tetric EvoFlow Test Pack 1x1.3g A3	CLASS IIA	8
759143WW	Tetric EvoFlow/Cannula Refill	CLASS IIA	8

Schaan, 13.02.2024

(this document is valid without signature)