

EU Declaration of Conformity for Class_Ila_6490189


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 EvoFlow
Basic-UDI-DI	76152082AFILL005JJ

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 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 CE 0123
Conformity Assessment Procedure (MDR Annex IX)	<input checked="" type="checkbox"/> Quality Management System <input type="checkbox"/> 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

Attachment to EU Declaration of Conformity

Article No.	Description	MDR Classification (EU)	Rule MDR (EU)
595953US	Tetric EvoFlow Refill 1x2g A1	Ila	8
595953WW	Tetric EvoFlow Refill 1x2g A1	Ila	8
595954US	Tetric EvoFlow Refill 1x2g A2	Ila	8
595954WW	Tetric EvoFlow Refill 1x2g A2	Ila	8
595955US	Tetric EvoFlow Refill 1x2g A3	Ila	8
595955WW	Tetric EvoFlow Refill 1x2g A3	Ila	8
595956WW	Tetric EvoFlow Refill 1x2g A3.5	Ila	8
595957WW	Tetric EvoFlow Refill 1x2g B3	Ila	8
595978WW	Tetric EvoFlow Refill 1x2g A4	Ila	8
595979US	Tetric EvoFlow Refill 1x2g T	Ila	8
595979WW	Tetric EvoFlow Refill 1x2g T	Ila	8
595980WW	Tetric EvoFlow Refill 1x2g A3.5 Dentin	Ila	8
595981WW	Tetric EvoFlow Refill 1x2g Bleach XL	Ila	8
595982WW	Tetric EvoFlow Refill 1x2g Bleach L	Ila	8
595984WW	Tetric EvoFlow Refill 1x2g Bleach M	Ila	8
595987US	Tetric EvoFlow Refill 20x0.2g A1	Ila	8
595987WW	Tetric EvoFlow Refill 20x0.2g A1	Ila	8
595988US	Tetric EvoFlow Refill 20x0.2g A2	Ila	8
595988WW	Tetric EvoFlow Refill 20x0.2g A2	Ila	8
595989US	Tetric EvoFlow Refill 20x0.2g A3	Ila	8
595989WW	Tetric EvoFlow Refill 20x0.2g A3	Ila	8
595990WW	Tetric EvoFlow Refill 20x0.2g A3.5	Ila	8
595991WW	Tetric EvoFlow Refill 20x0.2g B3	Ila	8
595992WW	Tetric EvoFlow Refill 20x0.2g A4	Ila	8
595993US	Tetric EvoFlow Refill 20x0.2g T	Ila	8
595993WW	Tetric EvoFlow Refill 20x0.2g T	Ila	8
595994WW	Tetric EvoFlow Ref. 20x0.2g A3.5 Dentin	Ila	8
595995WW	Tetric EvoFlow Refill 20x0.2g Bleach XL	Ila	8
595996WW	Tetric EvoFlow Refill 20x0.2g Bleach L	Ila	8
596008WW	Tetric EvoFlow Refill 20x0.2g Bleach M	Ila	8
641348WW	Tetric EvoFlow Refill 20x0.2g B1	Ila	8
641349WW	Tetric EvoFlow Refill 20x0.2g A2 Dentin	Ila	8
641350WW	Tetric EvoFlow Refill 20x0.2g B2 Dentin	Ila	8
641358WW	Tetric EvoFlow Refill 1x2g B1	Ila	8
641360WW	Tetric EvoFlow Refill 1x2g A2 Dentin	Ila	8
641361WW	Tetric EvoFlow Refill 1x2g B2 Dentin	Ila	8
700713WW	Tetric EvoFlow Test Pack 1x1.3g A2	Ila	8
700714WW	Tetric EvoFlow Test Pack 1x1.3g A3	Ila	8
759143WW	Tetric EvoFlow/Cannula Refill	Ila	8

Revision History			
Version	Date	Author	Remark
1.0	2023-10-27	R. Ritter	First MDR Version
2.0	2024-09-13	R. Ritter	APM110032
3.0	2024-12-17	R. Ritter	APM110714

Signing Page

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Document Approval (OTCS)

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