

EU Declaration of Conformity for Class_Class IIa_7943050


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 PowerFlow
Basic-UDI-DI	76152082AFILL008JQ

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 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)
692409WW	Tetric PowerFlow Refill 1 x 2g IVA	Ila	8
692410WW	Tetric PowerFlow Refill 1 x 2g IVB	Ila	8
692411WW	Tetric PowerFlow Refill 1 x 2g IVW	Ila	8
692413WW	Tetric PowerFlow Refill 20 x 0.2g IVA	Ila	8
692414WW	Tetric PowerFlow Refill 20 x 0.2g IVB	Ila	8
692415WW	Tetric PowerFlow Refill 20 x 0.2g IVW	Ila	8
692417WW	Tetric PowerFlow Test Pack 1x1.3g IVA	Ila	8
759144WW	Tetric PowerFlow/Cannula Refill	Ila	8

Revision History			
Version	Date	Author	Remark
1.0	2023-11-06	R. Ritter	First MDR Version
2.0	2024-11-27	R. Ritter	New GSPR (APM110390)

Signing Page

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Document Approval (OTCS)

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