

EU Declaration of Conformity for Class_Ila_9089043


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)	
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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.

Device under Assessment or Product(s)	Evetric
Basic-UDI-DI	76152082AFILL004JG

Legal manufacturer	
	Ivoclar Vivadent AG Bendererstrasse 2 9494 Schaan/Liechtenstein www.ivoclar.com

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  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)
639304AN	Evetric Refill 1x3.5g A2	Ila	8
639305AN	Evetric Refill 1x3.5g A3	Ila	8
639306AN	Evetric Refill 1x3.5g A3.5	Ila	8
639327AN	Evetric Refill 1x3.5g A3.5 Dentin	Ila	8
639668AN	Evetric Refill 1x3.5g A1	Ila	8
639669AN	Evetric Refill 1x3.5g B2	Ila	8
639670AN	Evetric Refill 1x3.5g B3	Ila	8
639671AN	Evetric Refill 1x3.5g C2	Ila	8
639672AN	Evetric Refill 1x3.5g T	Ila	8
639673AN	Evetric Refill 1x3.5g B2 Dentin	Ila	8
640102AN	Evetric Assortment 8x3.5g	Ila	8
759142AN	Evetric Assortment 4x3.5G	Ila	8

Document Revision History			
Version	Date	Author	Remark
1.0	2023-03-29	R. Ritter	First MDR Version
2.0	2024-05-24	R. Ritter	APM109319

Signing Page

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