EU Declaration of Conformity for Class_IIa_5939384

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)	**Evetric Bond**
Basic-UDI-DI	76152082ABOND005HS

Legal manufacturer		
ivoclar	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	Bonding of dental restorations to dental hard tissue, sealing of dentin lesions
Category (MDCG 2019-14)	MDN 1103 Non-active dental implants and dental materials
EMDN Code + term	Q01010104 Dental Bonding Agents
MDS Code	MDS 1007
MDT Code	MDT 2006 MDT 2011
EU Classification	☒ Medical Device ☐ Accessory for Medical Device
EU Risk Class (MDR Annex VIII)	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 Munich Germany
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)
668075AN	Evetric Bond Refill 1x6g	IIa	8

Revision History			
Version	**Date**	**Author**	**Remark**
1.0	2022-08-18	R. Ritter	First MDR Version
2.0	2023-02-23	R. Ritter	APM108156
3.0	2025-03-20	R. Ritter	New TEFO with updated Conformity Information

Signing Page

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Document Approval (OTCS)

UserName: Regina Ritter (RITTREG)
Title: Technical Assistant - Regulatory Affairs
Date: Friday, 21 March 2025, 09:54 W. Europe Daylight Time
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UserName: Sandro Sbicego (LISBC)
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UserName: Thomas Hirt (LIHIT)
Title: CTO
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