EU Declaration of Conformity for Class_IIa_5944243

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)	**Adhese Universal**
Basic-UDI-DI	76152082ABOND001HJ

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, conditioning of Tetric CAD restorations, 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 Risk Classification (MDR Annex VIII)	Medical Device 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 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)
753163	Adhese Universal VivaPen Refill 1x0,5ml	IIa	8
663720WW	Adhese Universal Refill Bottle 1x5g	IIa	8
663721WW	Adhese Universal Refill Bottle 2x5g	IIa	8
664505WW	Adhese Universal Refill VivaPen 3x2ml	IIa	8
665156WW	Adhese Universal Refill VivaPen 1x2ml	IIa	8
700710WW	Adhese Univ. Test Pack VivaPen 1x0.5ml	IIa	8
760299WW	Adhese Univ. Kit VivaPen 1x2ml/40	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	2024-12-17	R. Ritter	Updated TEFO

Signing Page

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Document Approval (OTCS)

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Title: Technical Assistant - Regulatory Affairs
Date: Tuesday, 17 December 2024, 16:06 W. Europe Daylight Time
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UserName: Sandro Sbicego (LISBC)
Title: Director Regulatory Affairs & Corporate Quality Control / PRRC
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