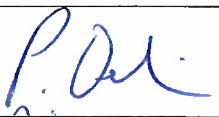
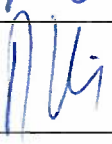
EU Declaration of Conformity according to Medical Device Regulation MDR 2017/745 Annex IV

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
Document-ID	OTCS5944243
Document Version	2.0

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	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. 00
Valid until	2026-05-04

Document Control			
Name	**Place of issue**	**Date of issue**	**Signature**
Approver (PRRC): Patrik Oehri	Schaan, LI	23.02.2023	
Approver (CTO): Dr. Thomas Hirt	Schaan, LI	23.02.2023	

Revision History			
Version	**Date**	**Author**	**Remark**
1.0	2022-08-18	Regina Ritter	First MDR Version
2.0	2023-02-23	Regina Ritter	APM108156

ivoclar

Attachment to EU Declaration of Conformity (MDR) of
ADHESE UNIVERSAL

Article No.	Description	MDR Classification (EU)	Rule MDR (EU)
000753163	Adhese Universal VivaPen Refill 1x0,5ml	CLASS IIA	8
663720WW	Adhese Universal Refill Bottle 1x5g	CLASS IIA	8
663721WW	Adhese Universal Refill Bottle 2x5g	CLASS IIA	8
664505WW	Adhese Universal Refill VivaPen 3x2ml	CLASS IIA	8
665156WW	Adhese Universal Refill VivaPen 1x2ml	CLASS IIA	8
700710WW	Adhese Univ. Test Pack VivaPen 1x0.5ml	CLASS IIA	8
760299WW	Adhese Univ. Kit VivaPen 1x2ml/40	CLASS IIA	8

Schaan, 12.02.2024

(this document is valid without signature)

The suffix of the article number (e.g. "AN", "EN", "AL", "WW") is only used for in-house reference and relates to the language version and/or electrical plug of the product. The suffix does not belong to the official article number.