

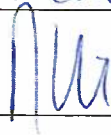
EU Declaration of Conformity according to Medical Device Regulation MDR 2017/745 Annex IV

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)	Variolink Esthetic DC
Basic-UDI-DI	76152082ACEME001DV
Document-ID	OTCS6622771
Document Version	2.0

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	LI-MF-000000522
Intended Purpose	Adhesive cementation of indirect anterior and posterior restorations
Category (MDCG 2019-14)	MDN 1103 Non-active dental implants and dental materials
EMDN Code + term	Q0101010201 Dental base cements
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

Document Control			
Name	Place of issue	Date of issue	Signature
Approver (PRRC): Dr. Thomas Völkel	Schaan, LI	12.02.2024	
Approver (CTO): Dr. Thomas Hirt	Schaan, LI	12.02.2024	

Revision History			
Version	Date	Author	Remark
1.0	2022-11-28	R. Ritter	First MDR Version
2.0	2024-02-08	R. Ritter	Variolink Esthetic Upgrade (DR494 OTCS134759899)

Attachment to EU Declaration of Conformity (MDR) of
VARIOLINK ESTHETIC DC

Article No.	Description	MDR Classification (EU)	Rule MDR (EU)
666117WW	Variolink Esthetic DC Refill 1x5g light+	CLASS IIA	8
666118WW	Variolink Esthetic DC Refill 1x5g light	CLASS IIA	8
666119WW	Variolink Esthetic DC Ref. 1x5g neutral	CLASS IIA	8
666120WW	Variolink Esthetic DC Refill 1x5g warm	CLASS IIA	8
666121WW	Variolink Esthetic DC Refill 1x5g warm+	CLASS IIA	8
666122WW	Variolink Esthetic DC Refill 1x9g light	CLASS IIA	8
666123WW	Variolink Esthetic DC Ref. 1x9g neutral	CLASS IIA	8
666124WW	Variolink Esthetic DC Refill 1x9g warm	CLASS IIA	8
692424WW	Variolink Esth. DC Refill 3x9g light	CLASS IIA	8
692425WW	Variolink Esth. DC Refill 3x9g neutral	CLASS IIA	8
692426WW	Variolink Esth. DC Refill 3x9g warm	CLASS IIA	8
762062WW	Variolink Esth DC Ref 1x5g White opaque	CLASS IIA	8

Schaan, 21.02.2024

(this document is valid without signature)