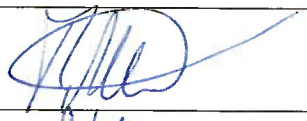
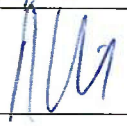
EU Declaration of Conformity according to Medical Device Regulation MDR 2017/745 Annex IV

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 LC**
Basic-UDI-DI	76152082ACEME004E3
Document-ID	OTCS6157118
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	Adhesive cementation of indirect, translucent anterior and posterior single-tooth 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		12.02.2024	
Approver (CTO): Dr. Thomas Hirt		12.02.2024	

Revision History			
Version	**Date**	**Author**	**Remark**
1.0	2022-08-18	R. Ritter	First MDR Version
2.0	2024-02-08	R. Ritter	Variolink Esthetic Upgrade (DR494 OTCS134759899)

ivoclar

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

Article No.	Description	MDR Classification (EU)	Rule MDR (EU)
666126WW	Variolink Esthetic LC Refill 1x2g light+	CLASS IIA	8
666127WW	Variolink Esthetic LC Refill 1x2g light	CLASS IIA	8
666128WW	Variolink Esthetic LC Ref. 1x2g neutral	CLASS IIA	8
666129WW	Variolink Esthetic LC Refill 1x2g warm	CLASS IIA	8
666130WW	Variolink Esthetic LC Refill 1x2g warm+	CLASS IIA	8
762061WW	Variolink Esth LC Ref 1x2g White opaque	CLASS IIA	8
763422WW	Variolink Esthetic LC Ref. 1x2g Warm+	CLASS IIA	8
763423WW	Variolink Esthetic LC Ref. 1x2g Warm	CLASS IIA	8
763424WW	Variolink Esthetic LC Ref. 1x2g Neutr	CLASS IIA	8
763425WW	Variolink Esthetic LC Ref 1x2g Light+	CLASS IIA	8
763446WW	Variolink Esthetic LC Ref. 1x2g Light	CLASS IIA	8

Schaan, 19.12.2024

(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.