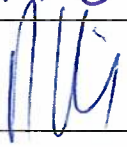
EU Declaration of Conformity according to Medical Device Regulation MDR 2017/745 Annex IV

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)	**GBT Visigate**
Basic-UDI-DI	76152081XDAMS001US
Document-ID	OTCS37694926
Document Version	1.0

Legal manufacturer		
ivoclar	Ivoclar Vivadent AG Benderer Strasse 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	Access to the oral cavity of the patient
EU Risk Classification (MDR Annex VIII)	Medical Device Class I CE
Conformity Assessment Procedure (MDR Annex IX)	Quality Management System
Notified Body Address	**TÜV SÜD Product Service GmbH** Ridlerstrasse 65 80339 München Deutschland
EC Certificate No.	N/A
Valid until	2026-05-04

Document Control			
Name	**Place of issue**	**Date of issue**	**Signature**
Approver (PRRC): Patrik Oehri	Schaan, LI	04.09.2023	
Approver (CTO): Dr. Thomas Hirt	Schaan, LI	06.09.2023	

Revision History			
Version	**Date**	**Author**	**Remark**
1.0	2023-09-04	R. Ritter	First MDR Version