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)	**VivaPen Sleeves**
Basic-UDI-DI	++DIVO1XSLEE002DG
Document-ID	LL3441680
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	Contamination protection	
Category (MDCG 2019-14)	MDN 1214	General non-active non-implantable devices used in health care and non-active non-implantable devices
EMDN Code + term	T0306	Patient protection device during clinical procedures
MDS Code	---	
MDT Code	MDT 2002 MDT 2011	
EU Risk Classification (MDR Annex VIII)	Medical Device Class I CE	
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.	☒ N/A	
Valid until	2025-07-15	

Document Control			
Name	**Place of issue**	**Date of issue**	**Signature**
Approver (PRRC): Patrik Oehri	Schaan, LI	17.08.2022	
Approver (CTO): Dr. Thomas Hirt	Schaan, LI	17.08.2022	

Revision History			
Version	**Date**	**Author**	**Remark**
1.0	2020-08-18	R. Ritter	First MDR Version
2.0	2022-08-16	R. Ritter	Update Basic UDI-DI