



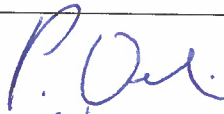
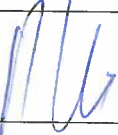
EU Declaration of Conformity according to Medical Device Regulation MDR 2017/745 Annex IV

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 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 
Conformity Assessment Procedure (MDR Annex IX)	<input checked="" type="checkbox"/> Quality Management System <input type="checkbox"/> Assessment of the Technical Documentation
Notified Body Address	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 München Deutschland
EC Certificate No.	<input checked="" type="checkbox"/> 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