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.

Products	CRS Set 10 CRS Set 15 CRS Set 20
Project Number(s) / Change Number(s)	none
Basic-UDI-DI	763081341XBITE001VU

Legal manufacturer	
CANDULOR	Candulor AG Boulevard Lilienthal 8 8152 Glattpark/Schweiz www.candulor.com

EU Declaration of Conformity Information	
SRN	CH-MF-000015795
Intended Purpose	Intraoral registration
EU Risk Classification (MDR Annex VIII)	Medical Device Class I CE
Conformity Assessment Procedure (MDR Annex IX)	Quality Management System
MDR Certificate No.	G20 090341 0017 Rev. 00
Valid until	2025-05-25

Attachment to EU Declaration of Conformity

Article No.	Description	MDR Classification (EU)	Rule MDR (EU)
662513	CRS Set 10	Class I	5, bullet 2
662521	CRS Set 15	Class I	5, bullet 2
681829	CRS Set 20	Class I	5, bullet 2

Document Control			
Name	**Place of issue**	**Date of issue**	**Signature**
Approver (PRRC)**:** Alexander Schwaszta	Glattpark, CH	2024-05-22	
Approver (Managing Director)**:** Claudia Schenkel-Thiel	Glattpark, CH	2024-05-22	

Document Revision History			
Version	**Date**	**Author**	**Remark**
1.0	2021-05-20	Miriam Stange	First MDR Version
2.0	2021-05-21	Miriam Stange	Correction of category product
3.0	2021-12-02	Miriam Stange	Correction of validity date
4.0	2024-05-16	Miriam Stange	Removal of Basic UDI-DI HIBC / use of Basic UDI-DI GS1 Removal of DE SRN Correction of validity date