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
Document-ID	LL3939848
Document Version	3.0
Legal Manufacturer information	CANDULOR **CANDULOR AG** Boulevard Lilienthal 8, 8152 Glattpark Switzerland Phone +41 (0)44 805 90 00, Fax +41 (0)44 805 90 00 www.candulor.com
SRN	CH-MF-000015795 DE-AR-000005472 DE-IM-000005475
Basic UDI-DI	++E1991XBITE001YK
Product	**CRS Set**
Intended Purpose	Intraoral registration
Category (MDCG 2019-14)	MDA Code: ☐ MDA 0311 Active non-implantable dental devices ☐ MDA 0315 Software MDN Code: ☐ MDN 1103 Non-active dental implants and dental materials ☒ MDN 1208 Non-active non-implantable instruments ☐ MDN 1209 Non-active non-implantable dental materials ☐ MDN 1214 General non-active non-implantable devices used in health care and non-active non-implantable devices
EMDN Code + term	Q010280 Devices for prosthetic dentistry - accessories
MDT Code	MDT2001 MDT2002 MDT2011
EU Risk Classification (MDR Annex VIII)	☒ Medical Device Class I CE ☐ Medical Device Class IIa CE 0123 ☐ Medical Device Class IIb CE 0123 ☐ Medical Device Class III CE 0123 see Notified Body below

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.	☒ not yet available ☐ N/A
Place and date of issue	Glattpark, 2021-12-02
Valid until	2024-05-24

Document Control		
Name	**Date**	**Signature**
Approver (PRRC): Alexander Schwaszta	02.12.2021	
Approver (Managing Director): Claudia Schenkel-Thiel	02.12.2021	

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