


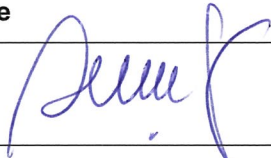

EU Declaration of Conformity according to Medical Device Regulation MDR 2017/745 Annex IV

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 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: <input type="checkbox"/> MDA 0311 Active non-implantable dental devices <input type="checkbox"/> MDA 0315 Software	
	MDN Code: <input type="checkbox"/> MDN 1103 Non-active dental implants and dental materials <input checked="" type="checkbox"/> MDN 1208 Non-active non-implantable instruments <input type="checkbox"/> MDN 1209 Non-active non-implantable dental materials <input type="checkbox"/> 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)	<input checked="" type="checkbox"/> Medical Device Class I CE <input type="checkbox"/> Medical Device Class IIa CE 0123 <input type="checkbox"/> Medical Device Class IIb CE 0123 <input type="checkbox"/> Medical Device Class III CE 0123	

see Notified Body below

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"/> not yet available <input type="checkbox"/> 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