Uncontrolled Record Print

Document Name:	Record-000005550 (2.0)
Document Title:	EU_Konformitätserklärung_CRS Set
Description:	EU_Konformitätserklärung_CRS Set
Document State:	Approved
Major Version change date:	24 May 2021 19:35:18 (GMT+02:00)
Print Information	This document is a confidential document not to be reproduced or shared.

Document Approval:

Signed By : Stange, Miriam (stanmir)
Decision : Approved
Decision Date : 21 May 2021 16:09:54 (GMT+02:00)
Role : Author
Purpose : DoC CRS Set V2.0
Meaning Of Signature : I have reviewed and hereby APPROVE the content and properties of this document(s)

Signed By : Schenkel-Thiel, Claudia (SCHECLA)
Decision : Approved
Decision Date : 21 May 2021 16:26:40 (GMT+02:00)
Role : Reviewer
Purpose : DoC CRS Set V2.0
Meaning Of Signature : I have reviewed and hereby APPROVE the content and properties of this document(s)

Signed By : Spalt, Jody Paul (SpalJod)
Decision : Approved
Decision Date : 24 May 2021 19:34:35 (GMT+02:00)
Role : Approver
Purpose : DoC CRS Set V2.0
Meaning Of Signature : I have reviewed and hereby APPROVE the content and properties of this document(s)

Printed By: Stange, Miriam (stanmir)

CANDULOR

EU Declaration of Conformity – CRS Set

Products	CRS Set 10 CRS Set 15 CRS Set 20
Document ID	LL 3939848
Document Version	1.0

Document Control		
Name	**Date**	**Signature**
Author (Product Manager): Miriam Stange	as per record management	
Approver (Head of Product Management & PRRC): Jody Paul Spalt	as per record management	
Approver (Managing Director): Claudia Schenkel - Thiel	as per record management	

Revision History			
Version	**Date**	**Author**	**Remark**
1.0	20.05.2021	Miriam Stange	First MDR Version
2.0	21.05.2021	Miriam Stange	Correction of category product

CANDULOR

.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.

Legal Manufacturer information	**CANDULOR AG** Boulevard Lilienthal 8 9494 8152 Glattpark (Opfikon) Switzerland	Phone +41 (0)44 805 90 00 Fax +41 (0)44 805 90 90 www.candulor.com Legal Form: Joint Stock Company
SRN	not yet available	
Basic UDI-DI	++E1991xBite001	
Product	**CRS Set**	
Category (NBOG F 2017-3)	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	
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, 2021-05-20	
Valid until	2026-05-20	

CANDULOR

Attachment to Declaration of conformity

Product group: **CRS Set**

Dated: 20.05.2021

Product	SAP No.
CRS Set 10	662513
CRS Set 15	662521
CRS Set 20	681829