

Uncontrolled Record Print

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Description:	EU Konformitätserklärung Bite Fork
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Document Approval:

Signed By : Spalt, Jody Paul (SpalJod)

Decision : Approved

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Role : Approver

Purpose : DoC Bite forc & CRS Set 2.0

Meaning Of Signature : I have reviewed and hereby APPROVE the content and properties of this document(s)

Signed By : Stange, Miriam (stanmir)

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Role : Author

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Signed By : Schenkel-Thiel, Claudia (SCHECLA)

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Printed By: Stange, Miriam (stanmir)

EU Declaration of Conformity – Bite Fork

Products	Bite Fork Bite Fork Set
Document ID	LL 3940585
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



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	+E1991xBite002	
Product	Bite Fork	
Category (NBOG F 2017-3)	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	
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, 2021-05-20	
Valid until	2026-05-20	

Attachment to Declaration of conformity

Product **Bite Fork**

Dated 20.05.2021

Product	SAP No.
Bite Fork	662451
Bite Fork Set	662453

Signed