

EU Declaration of Conformity for Class_Ila_NFC+_195457162

Document Information (OTCS)	
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Signatures	
Author(s)	The signatures of all involved signatories are added on the last page of this document.
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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	PhysioStar NFC+, Condyloform II NFC+, Bonartic II NFC+
Basic-UDI-DI	763081342APROS002VE

Legal manufacturer		
	Candulor AG Boulevard Lilienthal 8 8152 Glattpark/Schweiz www.candulor.com	Phone: +41 (0) 78 694 3311 www.candulor.com Legal Form: Joint Stock Corporation Corporate Headquarters: 8152 Glattpark Registration No.: CHE-107.821.754 VAT No.: CHE-107.821.754

EU Declaration of Conformity Information	
EC-REP	SRN: DE-AR-000005472 Candulor Dental GmbH Am Riederngraben 6 78238 Rielasingen-Worblingen Germany
SRN (Legal Manufacturer)	CH-MF-000015795
Intended Purpose	Replacement of missing teeth with rmovable dentures
Category (MDCG 2019-14)	MDN 1209 Non-active non-implantable dental materials
EMDN Code + term	Q010699
MDS Code	MDS 1007
MDT Code	MDT 2002 MDT 2006 MDT 2011
EU Classification	Medical Device
EU Risk Class (MDR Annex VIII)	Class IIa CE 0123
Conformity Assessment Procedure (MDR Annex IX)	<input checked="" type="checkbox"/> Quality Management System
Notified Body Address	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 Munich Germany
EC Certificate No.	G20 090341 0017 Rev. 00
Valid until	2028-11-01

Attachment to EU Declaration of Conformity

Article No.	Description	MDR Classification (EU)	Rule MDR (EU)
660100	Bonartic II NFC plus 8er	Ila	5
660209	Condyliform II NFC plus 8er	Ila	5
660912	PhysioStar NFC plus 6er	Ila	5

Revision History			
Version	Date	Author	Remark
1.0	2024-05-15	Miriam Stange	First MDR Version
2.0	2024-06-04	Miriam Stange	Correction of missing articles in "Attachment to EU DoC"
3.0	2025-02-11	Alexander Schwaszta	New Template, APM 111149

Signing Page

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Document Approval (OTCS)

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