

EU Declaration of Conformity for Class_Ila_PhysioSelect_11219722


Document Information (OTCS)	
OTCS – Doc.-ID	2.0
Version	

Signatures	
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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	PhysioSelect TCR, BonSelect TCR
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 Materials for the preparation of custom-made dental devices - other
MDS Code	MDS 1007
MDT Code	MDT 2002 MDT 2006 MDT 2011
EU Classification	Medical Device
EU Risk Classification (MDR Annex VIII)	Class IIa CE 0123
Conformity Assessment Procedure (MDR Annex IX)	Quality Management System
Notified Body Address	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 München Deutschland
MDR Certificate No.	G20 090341 0017 Rev. 00
Valid until	

Attachment to EU Declaration of Conformity

Article No.	Description	MDR Classification (EU)	Rule MDR (EU)
000696700	PhysioSelect TCR 6er	Ila	5
000698517	BonSelect TCR 8er	Ila	5

Revision History			
Version	Date	Author	Remark
1.0	2024-05-15	Miriam Stange	First MDR Version
2.0	2025-01-31	Alexander Schwaszta	2 nd . MDR Version (GSPR 2025-01-27)
3.0	2025-02-11	Alexander Schwaszta	Change 111419 – Removal RFID -label

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