

EU Declaration of Conformity for Class_414761020


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.
Reviewer(s)	
Approver(s)	

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	UCAN Mill: TCR Mono; TCR Multi
Basic-UDI-DI	763081342APROS005VL

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 Riedergraben 6 78238 Rielasingen-Worblingen Germany
SRN (Legal Manufacturer)	CH-MF-000015795
Intended Purpose	Fabrication of artificial teeth for removable 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	<input checked="" type="checkbox"/> 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	2028-11-02

Attachment to EU Declaration of Conformity

Article No.	Description	MDR Classification (EU)	Rule MDR (EU)
756197	TCR Mono BL3 98.5-20MM	Ila	5
756198	TCR Mono A1 98.5-20MM	Ila	5
756199	TCR Mono A2 98.5-20MM	Ila	5
756200	TCR Mono A3 98.5-20MM	Ila	5
756201	TCR Mono A3.5 98.5-20MM	Ila	5
756202	TCR Mono B1 98.5-20MM	Ila	5
756203	TCR Mono B3 98.5-20MM	Ila	5
756204	TCR Mono C2 98.5-20MM	Ila	5
756205	TCR Mono D2 98.5-20MM	Ila	5
756216	TCR Multi BL3 98.5-20MM	Ila	5
756217	TCR Multi A1 98.5-20MM	Ila	5
756218	TCR Multi A2 98.5-20MM	Ila	5
756219	TCR Multi A3 98.5-20MM	Ila	5
756220	TCR Multi A3.5 98.5-20MM	Ila	5
756221	TCR Multi B1 98.5-20MM	Ila	5
756222	TCR Multi B3 98.5-20MM	Ila	5
756223	TCR Multi C2 98.5-20MM	Ila	5
756224	TCR Multi D2 98.5-20MM	Ila	5

Revision History			
Version	Date	Author	Remark
1.0	2025-06-12	Alexander Schwazsta	First MDR Version
2.0	2025-07-25	Alexander Schwaszta	APM 111991 - RFID & Supplier – Change Package 1

Signing Page

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Document Approval (OTCS)

UserName: Antonio Ferilli (FERIANT)
Title: Head of Product Management
Date: Monday, 28 July 2025, 13:25 W. Europe Daylight Time
Meaning: I have reviewed and hereby APPROVE the content
and properties of this document(s) in my role as Creator
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UserName: Claudia Schenkel-Thiel (SCHECLA)
Title: Managing Director Candulor
Date: Monday, 04 August 2025, 08:15 W. Europe Daylight Time
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