EU Declaration of Conformity for Class_414758367

Document Information (OTCS)	
OTCS – Doc.-ID	414758367
Version	2.0

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	**X PLEX Base**
Basic-UDI-DI	763081342APROS006VN

Legal manufacturer		
CANDULOR	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	Fabrication of bases 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	☒ Medical Device	
EU Risk Class (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 Munich Germany	
EC Certificate No.	G20 090341 0017 Rev. 00	
Valid until	2028-11-0	

Attachment to EU Declaration of Conformity

Article No.	Description	MDR Classification (EU)	Rule MDR (EU)
756174	XPLEX Base 1 98.5-30MM	IIa	5
756175	XPLEX Base 5 98.5-30MM	IIa	5
756196	XPLEX Base 34 98.5-30MM	IIa	5

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

Signing Page

This is a representation of an electronic record that was signed electronically in Opentext Content Server. This page is the manifestation of the electronic signature(s) used in compliance with the organizations electronic signature policies and procedures.

Document Approval (OTCS)

UserName: Antonio Ferilli (FERIANT)
Title: Head of Product Management
Date: Monday, 28 July 2025, 13:26 W. Europe Daylight Time
Meaning: I have reviewed and hereby APPROVE the content and properties of this document(s) in my role as Creator
==========

UserName: Alexander Schwaszta (LISCHA)
Title: Director of QM/RA
Date: Monday, 28 July 2025, 14:33 W. Europe Daylight Time
Meaning: I have reviewed and hereby APPROVE the content and properties of this document(s) in my role as Approver
==========

UserName: Claudia Schenkel-Thiel (SCHECLA)
Title: Managing Director Candulor
Date: Monday, 04 August 2025, 08:12 W. Europe Daylight Time
Meaning: I have reviewed and hereby APPROVE the content and properties of this document(s) in my role as Approver
==========