EU Declaration of Conformity for Class_IIa_XPLEX_212297370

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	**X PLEX**
Basic-UDI-DI	763O81342APROS004VJ

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 removalbe 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 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	2028-11-02

Attachment to EU Declaration of Conformity

Article No.	Description	MDR Classification (EU)	Rule MDR (EU)
709543	X PLEX 150ml Monomer Cold	IIa	5
709544	X PLEX 500ml Monomer Cold	IIa	5
710657	X PLEX 150ml Monomer Hot	IIa	5
710658	X PLEX 500ml Monomer Hot	IIa	5
710848	X PLEX 100g F34	IIa	5
710849	X PLEX 100g F53	IIa	5
710850	X PLEX 100g F55	IIa	5
710851	X PLEX 100g F57	IIa	5
710854	X PLEX 500g F1	IIa	5
710896	X PLEX 500g F3	IIa	5
710900	X PLEX 500g F5	IIa	5
710902	X PLEX 500g F34	IIa	5
710913	X PLEX 6 x 500g F5	IIa	5
710916	X PLEX 6 x 500g F34	IIa	5

Revision History			
Version	**Date**	**Author**	**Remark**
1.0	2024-06-10	Miriam Stange	First MDR Version
2.0	2025-06.06	Alexander Schwaszta	1st. MDR PMS & new Template

Signing Page

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Document Approval (OTCS)

UserName: Antonio Ferilli (FERIANT)
Title: Head of Product Management
Date: Friday, 06 June 2025, 14:47 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: Alexander Schwaszta (LISCHA)
Title: Director of QM/RA
Date: Tuesday, 10 June 2025, 07:03 W. Europe Daylight Time
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UserName: Claudia Schenkel-Thiel (SCHECLA)
Title: Managing Director Candulor
Date: Thursday, 12 June 2025, 09:31 W. Europe Daylight Time
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