EU Declaration of Conformity for Class_IIa_254841978

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)	
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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.

Product	Baseplast
Basic-UDI-DI	763081342APROS004VJ

Legal manufacturer	
CANDULOR	Candulor AG Boulevard Lilienthal 8 8152 Glattpark/Schweiz www.candulor.com

EU Declaration of Conformity Information		
SRN (Legal Manufacturer)	CH-MF-000015795	
EC-REP	SRN: DE-AR-000005472 Candulor Dental GmbH Am Riedengraben 6 78238 Rielasingen-Worblingen Germany	
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 2006 MDT 2011	
EU Risk Classification (MDR Annex VIII)	Medical Device 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	
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)
000672729	BasePlast Polymer 500g F5	IIa	5
000672730	BasePlast Polymer 500g F6	IIa	5
000672731	BasePlast Polymer 500g F34	IIa	5
000674271	BasePlast Monomer 500ml	IIa	5

Document Revision History			
Version	**Date**	**Author**	**Remark**
1.0	2021-04-14	Miriam Stange	MDD-Version
2.0	2024-10-22	Alexander Schwaszta	1st.MDR Version

Signing Page

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