

EU Declaration of Conformity for Class_Ila_254803341


Document Information (OTCS)	
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Signatures	
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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	Autoplast
Basic-UDI-DI	763081342APROS004VJ

Legal manufacturer	
	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)	<input checked="" type="checkbox"/> 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)
000672726	AutoPlast Polymer 500g F5	IIa	5
000672727	AutoPlast Polymer 500g F6	IIa	5
000672728	AutoPlast Polymer 500g F34	IIa	5
000674270	AutoPlast 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	1 st .MDR Version

Signing Page

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