

EU Declaration of Conformity for Class_Class Ila_11131996


Document Information (OTCS)	
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Version	

Signatures	
Author(s)	The signatures of all involved signatories are added on the last page of this document.
Reviewer(s)	
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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	Product/ Product Group
Basic-UDI-DI	763081342APROS001VC

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	<ul style="list-style-type: none"> - Fabrication of bases for removable dentures - Fabrication of hard occlusal splints Fabrication of orthodontic appliances
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 I)	<input checked="" type="checkbox"/> Quality Management System

Notified Body Address	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 München Deutschland
EC Certificate No.	<input checked="" type="checkbox"/> G20 090341 0017 Rev. 00
Valid until	2028-11-01

Attachment to EU Declaration of Conformity

Article No.	Description	MDR Classification (EU)	Rule MDR (EU)
672710	AESTHETIC Red Polymer 100g F34	Ila	5
672711	AESTHETIC Red Polymer 100g F53	Ila	5
672712	AESTHETIC Red Polymer 100g F55	Ila	5
672713	AESTHETIC Red Polymer 100g F57	Ila	5
672714	AESTHETIC Red Polymer 500g F0	Ila	5
672715	AESTHETIC Red Polymer 500g F1	Ila	5
672716	AESTHETIC Red Polymer 500g F3	Ila	5
672717	AESTHETIC Red Polymer 500g F5	Ila	5
672718	AESTHETIC Red Polymer 500g F34	Ila	5
674254	AESTHETIC Red LT Modelling Monomer	Ila	5
674267	AESTHETIC Red Monomer 150ml	Ila	5
674268	AESTHETIC Red Monomer 500ml	Ila	5
676794	AESTHETIC Red Color Set Easy Mini	Ila	5
676795	AESTHETIC Red Color Set Easy	Ila	5
674555	AESTHETIC Red Color Set Easy Mini	Ila	5
674556	AESTHETIC Intensive Color 01 weiss 15g	Ila	5
674557	AESTHETIC Intensive Color 02 blau 15g	Ila	5
674558	AESTHETIC Intensive Color 03 rosa 15g	Ila	5
674559	AESTHETIC Intensive Color 04 rot 15g	Ila	5
674560	AESTHETIC Intensive Color 05 orange 15g	Ila	5
674561	AESTHETIC Intensive Color 06 braun 15g	Ila	5
674562	AESTHETIC Intensive Color 07 schwarz 15g	Ila	5
674563	AESTHETIC Intensive Color 08 gelb 15g	Ila	5
680284	AESTHETIC Intensive Color opaque 15g	Ila	5

Revision History			
Version	Date	Author	Remark
1.0	2024-03-13	Miriam Stange	First MDR Version
2.0	2024-11-14	Alexander Schwaszta	1 st . Revision Notified Body / inclusion EC-REP

Signing Page

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Document Approval (OTCS)

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Meaning: I have reviewed and hereby APPROVE the content
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UserName: Claudia Schenkel-Thiel (SCHECLA)
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