

EU Declaration of Conformity for Class_Ila_9477650


Document Information (OTCS)	
OTCS – Doc.-ID	9477650
Version	4.0

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	Aesthetic Blue, Aesthetic Blue Clear, Aesthetic Intensive Color & Opaque, Fibres, Aesthetic Blue LT Modelling Monomer
Basic-UDI-DI	763081342APROS001VC

Legal manufacturer		
	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 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 Classification	<input checked="" type="checkbox"/> Medical Device
EU Risk Class (MDR Annex VIII)	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 Munich Germany
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)
000672697	AESTHETIC Blue Polymer 100g F34	Ila	5
000672698	AESTHETIC Blue Polymer 100g F53	Ila	5
000672699	AESTHETIC Blue Polymer 100g F55	Ila	5
000672700	AESTHETIC Blue Polymer 100g F57	Ila	5
000672701	AESTHETIC Blue Polymer 500g F0	Ila	5
000672702	AESTHETIC Blue Polymer 500g F1	Ila	5
000672703	AESTHETIC Blue Polymer 500g F3	Ila	5
000672704	AESTHETIC Blue Polymer 500g F5	Ila	5
000672705	AESTHETIC Blue Polymer 500g F34	Ila	5
000674253	AESTHETIC Blue LT Modelling Monomer	Ila	5
000674265	AESTHETIC Blue Monomer 150ml	Ila	5
000674266	AESTHETIC Blue Monomer 500ml	Ila	5
000674555	AESTHETIC Intensive Color 01 weiss 15g	Ila	5
000674556	AESTHETIC Intensive Color 02 blau 15g	Ila	5
000674557	AESTHETIC Intensive Color 03 rosa 15g	Ila	5
000674558	AESTHETIC Intensive Color 04 rot 15g	Ila	5
000674559	AESTHETIC Intensive Color 05 orange 15g	Ila	5
000674560	AESTHETIC Intensive Color 06 braun 15g	Ila	5
000674561	AESTHETIC Intensive Color 07 schwarz 15g	Ila	5
000674562	AESTHETIC Intensive Color 08 gelb 15g	Ila	5
000674563	AESTHETIC Intensive Color opaque 15g	Ila	5
000676792	AESTHETIC Blue Color Set Easy Mini	Ila	5
000676793	AESTHETIC Blue Color Set Easy	Ila	5
000680284	Fibrillen 0,5g	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 Review Notified Body / EC-REP
3.0	2025-05-07	Alexander Schwaszta	APM 110784 / Neu Form

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: Thursday, 08 May 2025, 14:05 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: Thursday, 08 May 2025, 18:15 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: Tuesday, 13 May 2025, 14:26 W. Europe Daylight Time
Meaning: I have reviewed and hereby APPROVE the content
and properties of this document(s) in my role as Approver
=====