

EU Declaration of Conformity for Class I_I_Aesthetic Wax_76203075


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	Aesthetic Wax Aesthetic Color Wax Set
Basic-UDI-DI	763081341XWAX001QK

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	Dental Wax
Regulations and Directives	2017/745 Medical Device Regulation
EU Classification	<input checked="" type="checkbox"/> Medical Device
EU Risk Class (MDR Annex VIII)	Class I 
Conformity Assessment Procedure (MDR Annex IX)	Quality Management System
EC Certificate No.	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)
000662466	AESTHETIC Wax Soft 500g	I	5
000662467	AESTHETIC Wax Soft 2500g	I	5
000662468	AESTHETIC Wax Medium 500g	I	5
000662469	AESTHETIC Wax Hard 500g	I	5
000662473	AESTHETIC Color Wax Set 24g	I	5

Revision History			
Version	Date	Author	Remark
1.0	2021-05-25	Miriam Stange	1 st . MDR Version
2.0	2021-12-03	Miriam Stange	Correction of validity date
3.0	2025-05-23	Alexander Schwaszta	1 st .PMS MDR / new template

Change History

Reason for the preparation / revision:
 Update Phone Number of Sagemax Bioceramics Inc
 Add new row for Classification

Replaces the following documents:
 TEFO-EN-000422 Version 6.0

Signing Page

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Document Approval (OTCS)

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Date: Friday, 23 May 2025, 14:45 W. Europe Daylight Time
Meaning: I have reviewed and hereby APPROVE the content
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UserName: Alexander Schwaszta (LISCHA)
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