

## EU Declaration of Conformity for Class\_Ila\_9477650


| Document Information 9477650 |     |
|------------------------------|-----|
| OTCS – Doc.-ID               | 3.0 |
| Version                      |     |

| 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.

|                     |  |
|---------------------|--|
| <b>Products</b>     | <b>Aesthetic Blue, Aesthetic Blue Clear, Aesthetic Intensive Color &amp; Opaque, Fibres, Aesthetic Blue LT Modelling Monomer</b> |
| <b>Basic-UDI-DI</b> | 763081342APROS001VC  |

| Legal manufacturer  |  |  |
|---|--|--|
|  | <b>Candulor AG</b><br>Boulevard Lilienthal 8<br>8152 Glattpark/Schweiz<br>www.candulor.com | Phone: +41 (0) 78 694 3311<br>www.candulor.com<br>Legal Form: Joint Stock Corporation<br>Corporate Headquarters: 8152 Glattpark<br>Registration No.: CHE-107.821.754<br>VAT No.: CHE-107.821.754 |

| EU Declaration of Conformity Information              |   |
|---|---|
| <b>EC-REP</b>   | SRN: DE-AR-000005472<br>Candulor Dental GmbH<br>Am Riederngraben 6<br>78238 Rielasingen-Worblingen<br>Germany   |
| <b>SRN (Legal Manufacturer)</b>                       | CH-MF-000015795   |
| <b>Intended Purpose</b>                               | <ul style="list-style-type: none"> <li>- Fabrication of bases for removable dentures</li> <li>- Fabrication of hard occlusal splints</li> </ul> Fabrication of orthodontic appliances |
| <b>Category (MDCG 2019-14)</b>                        | MDN 1209      Non-active non-implantable dental materials   |
| <b>EMDN Code + term</b>                               | Q010699      Materials for the preparation of custom-made dental devices – other  |
| <b>MDS Code</b>                                       | MDS 1007  |
| <b>MDT Code</b>                                       | MDT 2006<br>MDT 2011  |
| <b>EU Risk Classification (MDR Annex VIII)</b>        | Medical Device Class IIa <span style="border: 1px solid black; padding: 2px;">CE 0482</span>  |
| <b>Conformity Assessment Procedure (MDR Annex IX)</b> | <input checked="" type="checkbox"/> Quality Management System   |

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

**Attachment to EU Declaration of Conformity**

| Article No.        | Description                              | MDR Classification (EU)             | Rule MDR (EU)             |
|--------------------|--|-------------------------------------|---------------------------|
| SAP Field "Objekt" | SAP Field "Bezeichnung"                  | SAP Field "MDR Classification (EU)" | SAP Field "Rule MDR (EU)" |
| 672697             | AESTHETIC Blue Polymer 100g F34          | Ila                                 | 5                         |
| 672698             | AESTHETIC Blue Polymer 100g F53          | Ila                                 | 5                         |
| 672699             | AESTHETIC Blue Polymer 100g F55          | Ila                                 | 5                         |
| 672700             | AESTHETIC Blue Polymer 100g F57          | Ila                                 | 5                         |
| 672701             | AESTHETIC Blue Polymer 500g F0           | Ila                                 | 5                         |
| 672702             | AESTHETIC Blue Polymer 500g F1           | Ila                                 | 5                         |
| 672703             | AESTHETIC Blue Polymer 500g F3           | Ila                                 | 5                         |
| 672704             | AESTHETIC Blue Polymer 500g F5           | Ila                                 | 5                         |
| 672705             | AESTHETIC Blue Polymer 500g F34          | Ila                                 | 5                         |
| 674253             | AESTHETIC Blue LT Modelling Monomer      | Ila                                 | 5                         |
| 674265             | AESTHETIC Blue Monomer 150ml             | Ila                                 | 5                         |
| 674266             | AESTHETIC Blue Monomer 500ml             | Ila                                 | 5                         |
| 674555             | AESTHETIC Intensive Color 01 weiss 15g   | Ila                                 | 5                         |
| 674556             | AESTHETIC Intensive Color 02 blau 15g    | Ila                                 | 5                         |
| 674557             | AESTHETIC Intensive Color 03 rosa 15g    | Ila                                 | 5                         |
| 674558             | AESTHETIC Intensive Color 04 rot 15g     | Ila                                 | 5                         |
| 674559             | AESTHETIC Intensive Color 05 orange 15g  | Ila                                 | 5                         |
| 674560             | AESTHETIC Intensive Color 06 braun 15g   | Ila                                 | 5                         |
| 674561             | AESTHETIC Intensive Color 07 schwarz 15g | Ila                                 | 5                         |
| 674562             | AESTHETIC Intensive Color 08 gelb 15g    | Ila                                 | 5                         |
| 674563             | AESTHETIC Intensive Color opaque 15g     | Ila                                 | 5                         |
| 680284             | Fibrillen 0,5g                           | Ila                                 | 5                         |
| 676792             | AESTHETIC Blue Color Set Easy Mini       | Ila                                 | 5                         |
| 676793             | AESTHETIC Blue Color Set Easy            | Ila                                 | 5                         |

| Revision History |             |                     |  |
|------------------|-------------|---------------------|--|
| Version          | Date        | Author              | Remark   |
| 1.0              | 2024-03-13  | Miriam Stange       | First MDR Version                              |
| 2.0              | 20204-11-14 | Alexander Schwazsta | 1 <sup>st</sup> .Review Notified Body / EC-REP |

## Signing Page

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**Document Approval (OTCS)**

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Title: Communication Manager  
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Meaning: I have reviewed and hereby APPROVE the content  
and properties of this document(s) in my role as Creator  
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UserName: Alexander Schwaszta (LISCHA)  
Title: Director of QM/RA  
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UserName: Claudia Schenkel-Thiel (SCHECLA)  
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Date: Wednesday, 27 November 2024, 17:51 W. Europe Daylight Time  
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