


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.

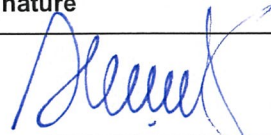
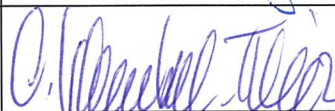
| | |
|-------------------------|---|
| Products | Aesthetic Red, Aesthetic Red Clear, Aesthetic Intensive & Opaque, Fibres, Aesthetic Red LT Modelling Monomer |
| Basic-UDI-DI | 763081342APROS001VC |
| Document-ID | OTCS1111131996 |
| Document Version | 1.0 |

| Legal manufacturer | | |
|---|--|--|
|  <small>CANDULOR</small> | 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 | |
|---|--|
| SRN | CH-MF-000015795 <i>(Candulor AG is non-EU manufacturer)</i> |
| 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 IX) | <input checked="" type="checkbox"/> Quality Management System |
| Notified Body Address | TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 München Deutschland |

Template ID: TEFO-03750-EN Version:14.0, Valid as of: 20 Feb 2024 08:01:58 (GMT+01:00)
 Template title: EU Declaration of Conformity for Class IIa, IIb, III
 Module: Device Registration (EU)
 Module owner: Head of Department Regulatory Documentation and Clinical Affairs

| | |
|---------------------------|---|
| EC Certificate No. | <input checked="" type="checkbox"/> G20 090341 0017 Rev. 00 |
| Valid until | 2028-11-02 |

| Document Control | | | |
|---|----------------|---------------|---|
| Name | Place of issue | Date of issue | Signature |
| Approver (PRRC): Alexander Schwaszta | Glattpark, CH | 13.03.2024 |  |
| Approver (MD): Claudia Schenkel-Thiel | Glattpark, CH | 13.03.2024 |  |

| Revision History | | | |
|------------------|------------|---------------|-------------------|
| Version | Date | Author | Remark |
| 1.0 | 2024-03-13 | Miriam Stange | First MDR Version |