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	OTCS111131996
Document Version	1.0

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	
SRN	CH-MF-000015795 *(Candulor AG is non-EU manufacturer)*
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 Risk Classification (MDR Annex VIII)	Medical Device Class IIa CE 0123
Conformity Assessment Procedure (MDR Annex IX)	☒ Quality Management System
Notified Body Address	**TÜV SÜD Product Service GmbH** Ridlerstrasse 65 80339 München Deutschland

EC Certificate No.	☒ 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