

EU Declaration of Conformity for Class I_I_C-Plast_32063562


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.
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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	C-Plast
Basic-UDI-DI	763081341XTRAY0018Z

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	Tray Material
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
Notified Body Address	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 Munich Germany
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)
672719	C-Plast Polymer 500g weiss	I	5
672722	C-Plast Polymer 500g F34	I	5
674272	C-Plast Monomer 500ml	I	5

Revision History			
Version	Date	Author	Remark
1.0	2020-07-20	Miriam Stange	First MDR Version
2.0	2021-12-02	Miriam Stange	Correction of validity date
3.0	2024-05-13	Miriam Stange	Removal of Basic UDI-DI HIBC / use of Basic UDI-DI GS1 Removal of DE SRN Correction of validity date
4.0	2025-05-21	Alexnader Schwaszta	1 st . PMS extension validity date and new form

Signing Page

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