

# EC Declaration of Conformity

Konformitätserklärung



## Declaration of conformity

CE 0123

Manufacturer  
Address  
Candulor AG  
Boulevard Lilienthal 8  
CH – 8152 Glattpark (Opfikon)  
Switzerland

Product  
**XPLEX**

Type of material  
Hot and cold curing denture base material

Product category  
Denture base material

Classification  
Medical Device Class IIa

We hereby declare under our exclusive responsibility that the above mentioned products meet the provisions of the following EC Council Directives and its implementation in national law. All supporting documentation is retained on the premises of the manufacturer and the notified body.

Directive  
Medical Device Directive 93/42/EEC, Annex V

Notified Body  
Address  
TÜV SÜD Product Service GmbH  
Ridlerstrasse 65  
80339 München  
Deutschland

Place, Valid from  
Glattpark, 28.10.2021  
Replaces version of: 05.01.2021

Valid until  
26.05.2024

Signature  
Name

  
Claudia Schenkel-Thiel

  
Alexander Schwaszta

Position

Managing Director

Head of QM & PRRC

Date

28.10.2021

28.10.2021

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## Attachment to Declaration of conformity

Product **XPLEX**

Dated 28.10.2021

| <b>PRODUCT</b>            | <b>ART.NR.</b> |
|---------------------------|----------------|
| X PLEX 100G F34           | 710848         |
| X PLEX 100G F53           | 710849         |
| X PLEX 100G F55           | 710850         |
| X PLEX 100G F57           | 710851         |
| X PLEX 150ML MONOMER COLD | 709543         |
| X PLEX 150ML MONOMER HOT  | 710657         |
| X PLEX 500G F1            | 710854         |
| X PLEX 500G F3            | 710896         |
| X PLEX 500G F34           | 710902         |
| X PLEX 500G F5            | 710900         |
| X PLEX 500ML MONOMER COLD | 709544         |
| X PLEX 500ML MONOMER HOT  | 710658         |
| X PLEX 6 X 500G F1        | 710907         |
| X PLEX 6 X 500G F3        | 710912         |
| X PLEX 6 X 500G F34       | 710916         |
| X PLEX 6 X 500G F5        | 710913         |
| X PLEX F34 TRIAL SET      | 711175         |