

EC Declaration of Conformity

Konformitätserklärung



Declaration of conformity

CE 0123

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

Product
BASEPLAST

Type of material
Heat-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, 14.04.2021
Replaces version of: 27.06.2017

Valid until
25.05.2024

Signature
Name


Claudia Schenkel-Thiel


Alexander Schwazla

Position

Managing Director

Director QM & RA

Date

14.04.2021

14.04.2021

EC Declaration of Conformity

Konformitätserklärung



Attachment to Declaration of conformity

Product **BASEPLAST**

Dated 14.04.2021

Product	SAP No.
BASEPLAST Polymer 500g F5 (pouch)	672729
BASEPLAST Polymer 500g F6 (pouch)	672730
BASEPLAST Polymer 500g F34 (pouch)	672731
BASEPLAST Monomer 500ml	674271