

EC Declaration of Conformity

Konformitätserklärung



Declaration of conformity

CE 0123

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

Product
AUTOPLAST

Type of material
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, 14.04.2021
Replaces version of: 27.06.2017

Valid until
25.05.2024

Signature
Name


Claudia Schenkel-Thiel


Alexander Schwazta

Position

Managing Director

Director QM & RA

Date

14.04.2021

14.04.2021

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Attachment to Declaration of conformity

Product **AUTOPLAST**

Dated 14.04.2021

Product	SAP No.
AUTOPLAST Polymer 100g F5	672723
AUTOPLAST Polymer 100g F6	672724
AUTOPLAST Polymer 100g F34	672725
AUTOPLAST Polymer 500g F5 (pouch)	672726
AUTOPLAST Polymer 500g F6 (pouch)	672727
AUTOPLAST Polymer 500g F34 (pouch)	672728
AUTOPLAST Monomer 150ml	674269
AUTOPLAST Monomer 500ml	674270