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Signed By : Stange, Miriam (stanmir)

Decision : Approved

Decision Date : 05 Jan 2021 08:51:17 (GMT+01:00)

Role : Author

Purpose : DoC XPLEX V2

Meaning Of Signature : I have reviewed and hereby APPROVE the content and properties of this document(s)

Signed By : Schenkel-Thiel, Claudia (SCHECLA)

Decision : Approved

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Role : Reviewer

Purpose : DoC XPLEX V2

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Signed By : Spalt, Jody Paul (SpalJod)

Decision : Approved

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Role : Approver

Purpose : DoC XPLEX V2

Meaning Of Signature : I have reviewed and hereby APPROVE the content and properties of this document(s)

Printed By: Stange, Miriam (stanmir)

EC Declaration of Conformity

Konformitätserklärung



Declaration of conformity

CE 0123

Manufacturer
Address Candolor 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, 05.01.2021
Replaces version of: 24.09.2020

Valid until 05.01.2026

Signature
Name _____
Claudia Schenkel-Thiel Jody Paul Spalt

Position Managing Director Product Manager

Date _____

EC Declaration of Conformity

Konformitätserklärung



Attachment to Declaration of conformity

Product **XPLEX**

Dated 05.01.2021

PRODUCT	ART.NR.
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