EC-Declaration of Conformity for Medical Devices

(in accordance with annex II of the Council Directive for Medical Devices 93/42/EEC)

Name of manufacturer: VOCO GmbH

Address: Anton-Flettner-Straße 1 - 3
27472 Cuxhaven
Germany

We declare that the product

Article: Polofil Supra

Type: Light-curing micro-hybrid restorative material

Item Number: see annex

Class: IIa

Rule: 8

corresponds to the regulations of the following Council Directive :
93/42/EEC for Medical Devices
and that we take full responsibility for issuing this declaration.

Name and address of notified body

MedCert GmbH
Pilatuspool 2
20355 Hamburg
Germany
Identification number : 0482

Valid as long as the certificate in accordance with 93/42 EEC is valid

City: Cuxhaven

Date: February 17, 2021

Dr. A. Lenz

Regulatory Affairs

EC-Declaration of Conformity for Medical Devices

(in accordance with annex II of the Council Directive for Medical Devices 93/42/EEC)

Name of manufacturer: VOCO GmbH

ANNEX

Article: Polofil Supra

REF #	Description
1360	Set Syringe 7 × 4 g (A1, A2, A3, A3.5, B2, B3, incisal), Vococid gel Syringe 5 ml, Solobond M bottle 4 ml
1361	Syringe 4 g A1
1362	Syringe 4 g A2
1363	Syringe 4 g A3
1364	Syringe 4 g A3.5
1365	Syringe 4 g B2
1366	Syringe 4 g B3
1368	Syringe 4 g incisal
1373	Set Syringe 3 × 4 g (A2, A3, A3.5), Vococid bottle 3 ml, Solobond M bottle 4 ml
1374	set Syringe 4 x 4 g
1375	Syringe sample

City: Cuxhaven

Date: February 17, 2021

Dr. A. Lenz

Regulatory Affairs