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: Ionofil Plus

Type: Glass ionomer 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: Ionofil Plus

REF #	Description
1520	Powder & liquid 3 × 15 g powder (A1, A2, A3), liquid bottle 10 ml, Final Varnish LC bottle 3 ml
1521	Powder 15 g A1
1522	Powder 15 g A3
1524	Liquid 10 ml
1525	Powder 15 g A2

City: Cuxhaven

Date: February 17, 2021

Dr. A. Lenz

Regulatory Affairs