

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: Bifluorid 10

Type: Fluoride varnish for the treatment of dental hypersensitivity

Item Number: see annex

Class: IIa

Rule: 5

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 16, 2021

Dr. A. Less

Regulatory Affairs

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

Name of manufacturer: VOCO GmbH

ANNEX

Article: Bifluorid 10

REF #	Description
1611	SingleDose Sample
1615	Bottle 4 g, Solvent bottle 10 ml
1616	Bottle 10 g
1617	Bottle 3 × 10 g, Solvent bottle 10 ml, Pele Tim No. 1
1618	SingleDose 50 pcs.
1619	SingleDose 200 pcs.

City: Cuxhaven

Date: February 16, 2021

Dr. A. Lenz

Regulatory Affairs