

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: Bifix SE

Type: Dual-curing self-adhesive composite-based luting system

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. 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: Bifix SE

REF #	Description
1784	Set QuickMix Syringe 3 × 5 g (universal, transparent, white-opaque)
1785	QuickMix Syringe 5 g universal
1786	QuickMix Syringe 5 g transparent
1787	QuickMix Syringe 5 g white-opaque
2961	Set QuickMix Syringe 3 x 5 g universal

City: Cuxhaven

Date: February 17, 2021

Dr. A. Lenz

Regulatory Affairs