

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: BrackFix

Type: Light-curing bracket bonding 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 18, 2021

Dr. A. Leitz

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: BrackFix

REF #	Description
1205	Set adhesive Syringe 2 × 4 g, primer bottle 6 ml
1206	Set SE adhesive Syringe 2 × 4 g, primer SE SingleDose 40 pcs.
1207	Adhesive Syringe 2 × 4 g
1208	Primer bottle 6 ml
1209	Primer SE SingleDose 50 pcs.

City: Cuxhaven

Date: February 18, 2021

Dr. A. Lenz

Regulatory Affairs