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: Grandtec

Type: Resin-impregnated light-curing glass-fibre strands for dental adhesive technique

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. 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: Grandtec

REF #	Description
1168	Glass fibre strands 5 × 55 mm
1169	Test Kit 5 glass fibre strands 55 mm each, model, application aids, GrandioSO Heavy Flow Syringe 2 × 2 g A3
1170	Sample stripes 5 x 55 mm

City: Cuxhaven

Date: February 18, 2021

Dr. A. Lenz

Regulatory Affairs