

## 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:** GrandioSO

**Type:** Universal nano-hybrid 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 18, 2021

*Dr. A. Less*

---

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: GrandioSO

REF #	Description
2600	Set Syringe 5 × 4 g (A2, A3, A3.5, GA3.25, GA5), shade guide
2601	Set + bond Syringe 5 × 4 g (A2, A3, A3.5, GA3.25, GA5), shade guide + Futurabond NR SingleDose 50 pcs.
2610	Syringe 4 g A1
2611	Syringe 4 g A2
2612	Syringe 4 g A3
2613	Syringe 4 g GA3.25
2614	Syringe 4 g A3.5
2615	Syringe 4 g A4
2616	Syringe 4 g GA5
2619	Syringe 4 g B1
2620	Syringe 4 g B2
2621	Syringe 4 g B3
2624	Syringe 4 g C2
2627	Syringe 4 g D3
2629	Syringe 4 g incisal
2630	Syringe 4 g OA1
2631	Syringe 4 g OA2
2633	Syringe 4 g OA3.5
2635	Syringe 4 g BL
2640	Set Caps 80 × 0.25 g (16 each of A2, A3, A3.5, GA3.25, GA5), shade guide
2646	Trial kit Caps 8 × 0.25 g (2 each of A2, A3, GA3.25, GA5), GrandioSO Heavy Flow Syringe 1 g A3, Dimanto 1 x large cup
2648	Caps Sample
2650	Caps 16 x 0,25 g A1
2651	Caps 16 x 0,25 g A2
2652	Caps 16 x 0,25 g A3
2653	Caps 16 x 0,25 g GA3.25
2654	Caps 16 x 0,25 g A3.5
2655	Caps 16 x 0,25 g A4
2656	Caps 16 x 0,25 g GA5
2659	Caps 16 x 0,25 g B1
2660	Caps 16 x 0,25 g B2
2661	Caps 16 x 0,25 g B3
2664	Caps 16 x 0,25 g C2
2667	Caps 16 x 0,25 g D3
2669	Caps 16 x 0,25 g incisal
2670	Caps 16 x 0,25 g OA1
2671	Caps 16 x 0,25 g OA2
2673	Caps 16 x 0,25 g OA3.5
2675	Caps 16 x 0,25 g BL
2979	Caps 80 x 0,25 g A3
2980	Syringe 5 x 4 g A3

City: Cuxhaven

Date: February 18, 2021

*Dr. A. Leitz*

Regulatory Affairs