

## **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 Heavy Flow

**Type:** Flowable universal nano-hybrid restorative material – highly viscous

**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*

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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: GrandioSO Heavy Flow

REF #	Description
2680	Set Syringe 5 × 2 g (A2, A3, A3.5, WO, GA5), shade guide
2684	Syringe 2 x 2 g A1
2685	Syringe 2 x 2 g A2
2686	Syringe 2 x 2 g A3
2687	Syringe 2 x 2 g A3.5
2688	Syringe 2 x 2 g A4
2689	Syringe 2 x 2 g GA5
2690	Syringe 2 x 2 g B1
2691	Syringe 2 x 2 g B2
2692	Syringe 2 x 2 g C2
2693	Syringe 2 x 2 g OA2
2694	Syringe 2 x 2 g incisal
2695	Syringe 2 x 2 g BL
2696	Syringe 2 x 2 g WO
2699	Syringe sample
2704	Caps 16 x 0,25 g A1
2705	Caps 16 x 0,25 g A2
2706	Caps 16 x 0,25 g A3
2707	Caps 16 x 0,25 g A3.5
2708	Caps 16 x 0,25 g A4
2712	Caps 16 x 0,25 g B1

City: Cuxhaven

Date: February 18, 2021

*Dr. A. Lenz*

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