

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: Admira Fusion

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

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ANNEX

Article: Admira Fusion

REF #	Description
2750	Set + bond Syringe 5 × 3 g (A2, A3, GA3.25, A3.5, Admira Fusion x-tra), shade guide + Futurabond U SingleDose 20 pcs.
2751	Syringe 5 x 3 g A3
2754	Syringe 3 g A1
2755	Syringe 3 g A2
2756	Syringe 3 g A3
2757	Syringe 3 g GA3.25
2758	Syringe 3 g A3.5
2759	Syringe 3 g A4
2760	Syringe 3 g GA5
2762	Syringe 3 g B1
2763	Syringe 3 g B2
2764	Syringe 3 g B3
2766	Syringe 3 g C2
2768	Syringe 3 g D3
2770	Syringe 3 g OA1
2771	Syringe 3 g OA2
2772	Syringe 3 g OA3
2773	Syringe 3 g OA3.5
2775	Syringe 3 g BL
2776	Syringe 3 g Inzisal
2778	Trial kit Caps 9 × 0.2 g (3 each of A2, A3, A3.5), Admira Fusion Flow Syringe 2 g A3, Admira Fusion x-tra Caps 3 × 0.2 g universal
2779	Set Sample
2780	Set + bond Caps 75 × 0.2 g (15 each of A2, A3, GA3.25, A3.5, Admira Fusion x-tra), shade guide + Futurabond U SingleDose 20 pcs.
2781	Caps 75 x 0,2 g A3
2782	Caps 15 x 0,2 g A1
2783	Caps 15 x 0,2 g A2
2784	Caps 15 x 0,2 g A3
2785	Caps 15 x 0,2 g GA3.25
2786	Caps 15 x 0,2 g A3.5
2787	Caps 15 x 0,2 g A4
2788	Caps 15 x 0,2 g GA5
2790	Caps 15 x 0,2 g B1
2791	Caps 15 x 0,2 g B2
2792	Caps 15 x 0,2 g B3
2794	Caps 15 x 0,2 g C2
2796	Caps 15 x 0,2 g D3
2798	Caps 15 x 0,2 g OA1
2799	Caps 15 x 0,2 g OA2
2800	Caps 15 x 0,2 g OA3
2801	Caps 15 x 0,2 g OA3.5
2803	Caps 15 x 0,2 g BL
2804	Caps 15 x 0,2 g incisal
2806	Caps 15 x 0,2 g mixed
2809	Caps Sample

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Date: February 18, 2021

Dr. A. Leitz

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