

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: Grandio

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 17, 2021

Dr. A. Less

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: Grandio

REF #	Description
1800	Set Syringe 5 × 4 g (A1, A2, A3, A3.5, B2), shade guide
1801	Set + bond Syringe 5 × 4 g (A1, A2, A3, A3.5, B2), shade guide + Futurabond NR SingleDose 50 pcs.
1802	Set Syringe 3 × 4 g (A1, A2, A3), Solobond M bottle 4 ml, Vococid Syringe 5 ml, shade guide
1803	Set Syringe 5 × 4 g (2 x A2, 2 x A3, OA2), shade guide
1808	Syringe sample
1810	Syringe 4 g A1
1811	Syringe 4 g A2
1812	Syringe 4 g A3
1813	Syringe 4 g A3.5
1814	Syringe 4 g A4
1815	Syringe 4 g B2
1816	Syringe 4 g B3
1817	Syringe 4 g C2
1818	Syringe 4 g C3
1819	Syringe 4 g D3
1820	Syringe 4 g incisal
1821	Syringe 4 g OA2
1822	Syringe 4 g OA3.5
1823	Syringe 4 g BL
1824	Syringe 4 g B1
1825	Syringe 4 g D2
1830	Set Caps 50 × 0.25 g (10 each of A1, A2, A3, A3.5, B2), shade guide
1838	Caps Sample
1840	Caps 20 x 0,25 g A1
1841	Caps 20 x 0,25 g A2
1842	Caps 20 x 0,25 g A3
1843	Caps 20 x 0,25 g A3.5
1844	Caps 20 x 0,25 g A4
1845	Caps 20 x 0,25 g B2
1846	Caps 20 x 0,25 g B3
1847	Caps 20 x 0,25 g C2
1848	Caps 20 x 0,25 g C3
1849	Caps 20 x 0,25 g D3
1850	Caps 20 x 0,25 g incisal
1851	Caps 20 x 0,25 g OA2
1852	Caps 20 x 0,25 g OA3.5
1853	Caps 20 x 0,25 g BL
1854	Caps 20 x 0,25 g B1
1855	Caps 20 x 0,25 g D2
2928	Syringe 5 x 4 g A 3
2929	Caps 100 x 0,25 g A3

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Date: February 17, 2021

Dr. A. Lewitz

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