

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: Amaris

Type: Highly aesthetic light-curing 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 16, 2021

Dr. A. Less

Regulatory Affairs

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ANNEX

Article: Amaris

REF #	Description
1930	Set Syringe 8 × 4 g (O1, O2, O3, O4, O5, TL, TN, TD), Amaris Flow Syringe 2 × 1.8 g (HT, HO), shade guide
1931	Set + bond Syringe 8 × 4 g (O1, O2, O3, O4, O5, TL, TN, TD), Amaris Flow Syringe 2 × 1.8 g (HT, HO), shade guide + Futurabond NR SingleDose 50 pcs.
1932	Set Syringe 5 × 4 g (O1, O2, TL, TN, TD), shade guide
1933	Syringe 4 g O1
1934	Syringe 4 g O2
1935	Syringe 4 g O3
1936	Syringe 4 g O4
1937	Syringe 4 g O5
1938	Syringe 4 g O Bleach
1940	Syringe 4 g TL
1941	Syringe 4 g TN
1942	Syringe 4 g TD
1949	Starter set Caps 32 × 0.25 g (4 each of O1, O2, O3, O4, O5, TL, TN, TD), Amaris Flow Syringe 2 × 1.8 g (HT, HO), shade guide
1950	Set Caps 128 × 0.25 g (16 each of O1, O2, O3, O4, O5, TL, TN, TD), Amaris Flow Syringe 2 × 1.8 g (HT, HO), shade guide
1953	Caps 16 x 0,25 g O1
1954	Caps 16 x 0,25 g O2
1955	Caps 16 x 0,25 g O3
1956	Caps 16 x 0,25 g O4
1957	Caps 16 x 0,25 g O5
1958	Caps 16 x 0,25 g O Bleach
1960	Caps 16 x 0,25 g TL
1961	Caps 16 x 0,25 g TN
1962	Caps 16 x 0,25 g TD

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