

EC Certificate of Conformity

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH Pilatuspool 2-20355 Hamburg — Germany

herewith certifies that the company:

VOCO GmbH Anton-Flettner-Str. 1-3 27472 Cuxhaven Germany

has introduced, applies and maintains a quality assurance system for the products / product categories listed in the appendix.

The compliance of this quality assurance system with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex II without section 4

This certification is subject to surveillance by MEDCERT.

Effective date: 2021-03-01 Expiry date: 2024-05-27

Report No.: 0675FS28F Process No.: QS – 0675

Certificate No.: 0675GB410210301A

Hamburg, 2021-03-01

MEDCERT Certification Body (Dr. Andreas Schich)

The certificate is only valid when provided entirely with all of its pages. To verify the validity of this certificate, contact info@medcert.de.

MEDCERT Identification Number: 0482



Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten ZLG-BS-237.10.15



Appendix of EC Certificate of Conformity

Process No.:

QS - 0675

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List of products / product categories included in the scope of certificate

Dental materials and -instruments

- Luting materials (cements, polymers)
- Bleaching agents for internal and external dental bleaching, professional dental use only
- Dentine and enamel adhesives
- Endodontic filling materials
- Pit and fissure sealants
- Materials for generative production (3D printing) of dental forms (plastics)
- Materials for caries diagnosis
- Plastic materials for direct insertion (polymers)
- Materials for temporary filling and luting
- Temporary crown- and bridge materials
- Pulp capping materials
- Protective films (long term)
- Cavity lining materials
- Materials for fixed prostheses (inlays, onlays, crowns, bridges, veneers)
- Materials for removable prostheses (polymers)
- Materials for surface preparation (etch, prime)
- Rotary instruments for connection to dental handpieces (polisher, abrasives)

- End of list -

This appendix is integral part of the above-referenced certificate.

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