

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

Form F10010005e EN / Rev. 11 / 2019.11.14



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

Appendix of EC Certificate of Conformity

Process No.: QS – 0675

Certificate No.: 0675GB410210301A

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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MEDCERT Identification Number: 0482



Certificate

The certification 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 management system in the area of:

Design and development, manufacture, final inspection and distribution of
Dental materials, -instruments and -equipment as listed in the appendix

The conformity of this quality management system to the requirements of the below mentioned standard was verified by an audit:

EN ISO 13485:2016

This certification is subject to surveillance by MEDCERT.

Effective date: **2021-03-01**

Expiry date: **2024-03-01**

Report No.: 0675FS28F

Procedure No.: QS – 0675

Certificate No.: 0675GB445210301A

Hamburg, 2021-03-01



MEDCERT Certification Body
(Dr. Andreas Schich)

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MEDCERT is a DAkkS accredited management systems
certification body

Appendix of certificate

Procedure No.: QS – 0675

Certificate No.: 0675GB445210301A

List of products included in the scope of certificate

- Impression trays
- Impression materials
- Application aids
- Articulating, occlusion and bite registration devices
- 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
- Interdental wedges
- Rubber dam
- Materials for generative production (3D printing) of dental forms (plastics)
- Materials for caries diagnosis
- Matrix bands
- Mixers and mixing aids
- Plastic materials for direct insertion (polymers and auxiliaries)
- Polishing pastes
- Materials for temporary filling and luting
- Temporary crown- and bridge materials
- Pulp capping materials
- Cleaner for instruments and impression trays
- Protective films (long term)
- Protective films (varnish)
- Cavity lining materials
- Materials for fixed prostheses (inlays, onlays, crowns, bridges, veneers)
- Materials for removable prostheses (polymers)
- Materials for surface preparation (etch, prime)
- Retraction materials
- Rotary instruments for connection to dental handpieces (polisher, abrasives)
- Dental curing light with handpieces

– End of list –

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