

# Certificate

The Certification Body

**MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH  
Pilatuspool 2 – 20355 Hamburg – Deutschland**

herewith certifies that the company

**VOCO GmbH  
Anton-Flettner-Straße 1-3  
27472 Cuxhaven  
Germany**

has introduced, applies and maintains a quality management system in the area of activities, products/services and locations listed in the appendix.

The conformity of this quality management system to the requirements of the following standard and country-specific requirements of the following jurisdictions<sup>1</sup> has been verified by an audit:

**ISO 13485:2016  
Australia, Brazil, Canada, United States of America**

This certification is subject to surveillance by MEDCERT.

**Effective date: 2022-03-18**

**Expiry date: 2024-03-18**

Report No.: QS0675SA30F  
Procedure No.: QS – 0675  
Certificate No.: 0675GB451220318A

Hamburg, 2022-03-18

\_\_\_\_\_  
MEDCERT Certification Body  
Markus Bianchi

<sup>1</sup> Individual country-specific requirements are listed in the appendix.

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

MEDCERT is an MDSAP authorised auditing organisation.

## Appendix of certificate

Procedure No.: QS – 0675  
Certificate No.: 0675GB451220318A

### Activities and products/services in the scope of certification

Design and development, manufacture and distribution of

- Dental materials, -instruments and –equipment:
  - 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
  - Retraction 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)
  - Rotary instruments for connection to dental handpieces (polisher, abrasives)
  - Dental curing light with handpieces

### Country-specific requirements implemented in the quality management system

**Australia** – Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 (without 1.6)

**Brazil** – RDC ANVISA n. 16/2013; RDC ANVISA n. 23/2012; RDC ANVISA n. 67/2009

**Canada** – Medical Devices Regulations SOR/98-282, Part 1 (applicable requirements)

**United States of America** – 21 CFR 803; 21 CFR 806; 21 CFR 807 (Subparts A to D); 21 CFR 820

This appendix is integral part of the above-referenced certificate.  
The certificate is only valid when provided entirely with all of its pages.  
To verify the validity of this certificate, contact [info@medcert.de](mailto:info@medcert.de).

MEDCERT is an MDSAP authorised auditing organisation.

## Appendix of certificate

Procedure No.: QS – 0675  
Certificate No.: 0675GB451220318A

### Locations in the scope of certification

**VOCO GmbH**  
**Anton-Flettner-Straße 1-3**  
**27472 Cuxhaven**  
**Germany**  
Facility ID: F006052

Design and development, manufacture and distribution of

- Dental materials, -instruments and –equipment:
  - 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
  - Retraction 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)
  - Rotary instruments for connection to dental handpieces (polisher, abrasives)
  - Dental curing light with handpieces

This appendix is integral part of the above-referenced certificate.  
The certificate is only valid when provided entirely with all of its pages.  
To verify the validity of this certificate, contact [info@medcert.de](mailto:info@medcert.de).

MEDCERT is an MDSAP authorised auditing organisation.