

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 jurisdictions¹ 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:

Expiry date:

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

Hamburg, 2022-03-18

MEDCERT Certification Body
Markus Bianchi

¹ 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.

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.
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Appendix of certificate

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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:
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 - Articulating, occlusion and bite registration devices
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