

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 –

This appendix is integral part of the above-referenced certificate.
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Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*¹
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	VOCO GmbH
Manufacturer address and contact details	Anton-Flettner-Strasse 1-3 27472 Cuxhaven Germany
Single Registration Number (SRN) (if available)	DE-MF-000008601

Authorised Representative name (if applicable)	not applicable
Authorised Representative address and contact details	
Single Registration Number (SRN) (if available)	

Notified body name (if applicable)	DNV MEDCERT GmbH ☐ See attached schedule
Notified body number (if applicable)	0482 ☐ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	0675GB410210301A ☐ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	2024-05-27 ☐ See attached schedule

¹ The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

End date of extended validity/transition period	2028-12-31	☐ See attached schedule
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We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*²
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➤ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

Choose applicable statements:

☐ Expired *before* 20 March 2023:

- ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or
- ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or
- ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

- ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

² The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

- ☒ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

- ☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➤ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

- ☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➤ **Quality Management System (QMS)**

Choose one applicable statement:

- ☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
- ☐ A QMS in accordance with Article 10(9) MDR is in place.
- ☒ A notified body has issued the attached certificate for the MDR-compliant QMS.

➤ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

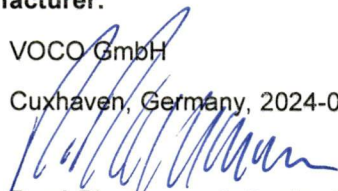
Full Company Name

VOCO GmbH

Location & Date

Cuxhaven, Germany, 2024-04-17

Signature, Print Name, Title


René Plaumann, Authorized Officer

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



Contact Details (at least email)

info@voco.de

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s) ³ (e.g., device name, family/group name, device model or catalogue number)	Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
Devices for conservative dentistry and endodontics	Certificate 0675GB410210301A	2024-05-27	DNV MEDCERT GmbH NB0482	DNV MEDCERT GmbH NB0482	2028-12-31	not applicable
Devices for prosthetic dentistry	Certificate 0675GB410210301A	2024-05-27	DNV MEDCERT GmbH NB0482	DNV MEDCERT GmbH NB0482	2028-12-31	not applicable
Surgical dental devices	Certificate 0675GB410210301A	2024-05-27	DNV MEDCERT GmbH NB0482	DNV MEDCERT GmbH NB0482	2028-12-31	not applicable
Orthodontic devices	Certificate 0675GB410210301A	2024-05-27	DNV MEDCERT GmbH NB0482	DNV MEDCERT GmbH NB0482	2028-12-31	not applicable
Instruments for dentistry, single-use	Certificate 0675GB410210301A	2024-05-27	DNV MEDCERT GmbH NB0482	DNV MEDCERT GmbH NB0482	2028-12-31	not applicable
Dental floss and other devices for oral hygiene (for professional use)	Certificate 0675GB410210301A	2024-05-27	DNV MEDCERT GmbH NB0482	DNV MEDCERT GmbH NB0482	2028-12-31	not applicable

³ for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)