

EU Quality Management System Certificate

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

SRN: DE-MF-000008601

has introduced, applies and maintains a quality management system for the medical devices/groups of medical devices listed in the appendix.

The compliance of this quality management system to the requirements of the **Regulation (EU) 2017/745 on medical devices** was verified by assessment according to:

Annex IX Chapter I

Any applicable limitations of this certification for certain medical devices are included in the appendix. This certification is subject to surveillance by MEDCERT.

Effective date: 2021-09-22
Expiry date: 2026-01-21

Final assessment report No.: 0675IA28F
Procedure No.: QS – 0675
Certificate No.: 0675GB448210922

Preceding certificate No.: —
Preceding certificate date: —
Identification of changes: —

Hamburg, 2021-09-22


MEDCERT Certification Body
(Marcus Harder)

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To verify the validity of this certificate, contact info@medcert.de.

MEDCERT Identification Number: 0482



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Zentralstelle der Länder
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Medizinprodukten
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BS-MDR-096

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Appendix of EU Quality Management System Certificate

Procedure No.: QS – 0675

Certificate No.: 0675GB448210922

Class IIa medical devices

Category of devices	Medical devices/groups of medical devices
MDN 1103	Q010101 Dental restorative devices Q010499 Orthodontic devices – others Q010699 Dentistry devices, fabrication materials - others
MDN 1209	Q010104 Dental procedures devices - various Q010201 Dental impression materials, alginates and others Q010206 Dental prostheses Q010399 Surgical dental devices – others Q010503 Dental impression material trays, single-use Q019003 Dental floss and other devices for oral cleansing (for professional use) Q010204 Retraction wires and gingival retractors

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