

CERTIFICATE

Number: 2243921

The management system of the organization(s) and locations mentioned on the addendum belonging to:

DeltaMed GmbH

Raiffeisenstrasse 8a
61169 Friedberg
Germany

Manufacturer Facility Identifier F003088

Conforms with the following standard and regulatory requirements:

ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002 and Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Brazil: RDC ANVISA n. 665/2022, 551/2021 and 67/2009
Canada: Medical Devices Regulations - Part 1- SOR 98/282
Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68 and PMD Act
United States: 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D and 21 CFR 820

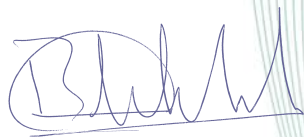
Scope:

Design and development, production and distribution of dental composites, dental crown and bridge materials, light-curing dental resins, bleaching agents for dental applications, denture resins, dental bite splint materials and contract manufacturing for lubrication gels for diaphragms and condoms.

Certificate expiry date: 2026-02-01
Certificate effective date: 2024-07-19
Certified since: 2020-02-01

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.M. McKenzie
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

The validation of the validity of this certificate can be checked through DEKRA's website using the following link:
<https://www.dekra-checkme.com/org>

DEKRA Certification B.V. is recognized under the Medical Devices Single Audit Program.



ADDENDUM

To certificate: 2243921

The management system of the organization(s) and/or location(s) of:

DeltaMed GmbH

Raiffeisenstrasse 8a
61169 Friedberg
Germany

Certified organization(s) and/or locations:

Different scope

DeltaMed GmbH
Raiffeisenstrasse 16
61169 Friedberg
Germany
Facility Identifier F003088

Manufacture of dental composites, dental crown and bridge materials, light-curing dental resins, bleaching agents for dental applications, denture resins, light-curing resins for ear-moulds, dental bite splint materials and contract manufacturing for lubrication gels for diaphragms and condoms

Addendum expiry date: 2026-02-01
Addendum effective date: 2024-07-19