

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 DUNS 344805101

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. 16/2013, 23/2012 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

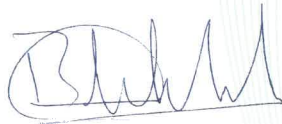
Scope:

Design and development, manufacture and distribution of composite dental filling materials and accessories (dental adhesive systems), light curing gingival protections, dental bleaching materials, dental splint materials and dental metal resin bonding systems as well as lubricating jelly for diaphragms and condoms

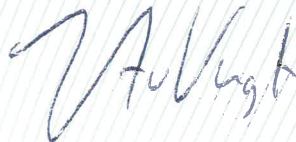
Certificate expiry date: 2023-02-01
Certificate effective date: 2020-02-01
Certified since: 2020-02-01

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.A. van Vugt
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-product-safety.com/en/certified-organizations>

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
DUNS: 314985575

Manufacture of composite dental filling materials and accessories (dental adhesive systems), light curing gingival protections, dental bleaching materials, dental splint materials and dental metal resin bonding systems as well as lubricating jelly for diaphragms and condoms

Addendum expiry date: 2023-02-01

Addendum effective date: 2020-02-01