



MANAGEMENT SYSTEM CERTIFICATE

Certificate no.
0439GB451230307

Final assessment report no.
0439AU32F

Effective date
2023-03-07

Expiry date
2025-09-13

This is to certify that the management system of

MERZ DENTAL GmbH

Kieferweg 1, 24321 Lütjenburg, Germany

Facility ID: F006037

With the sites as mentioned on the following pages

Has been found to conform to the quality management system standard

ISO 13485:2016 and the following country-specific requirements

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1
Brazil: RDC ANVISA n. 665/2022; RDC ANVISA n. 551/2021; RDC ANVISA n. 67/2009
Canada: Medical Devices Regulations (SOR/98-282) – Part 1 (applicable requirements)
Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68; PMD Act (as applicable)
United States: 21 CFR 803; 21 CFR 806; 21 CFR 807; 21 CFR 820

This certificate is valid for the scope of activities and products/services indicated on the following pages.

Place and date
Hamburg, 2023-03-07

For the issuing office
DNV MEDCERT GmbH
Pilatuspool 2, 20355 Hamburg, Germany

DNV MEDCERT is an MDSAP
authorised auditing organisation

Markus Bianchi
Director Certification Body

The certificate is only valid when provided entirely with all of its pages. To verify the validity of this certificate, contact info@medcert.de

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

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AUTHORISED UNIT: DNV MEDCERT GmbH (previously: MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH)
Pilatuspool 2, 20355 Hamburg, Germany, Tel +49 40 2263325-0, www.med-cert.com, www.dnv.com

Activities and products/services covered by this certificate

Design and development, manufacture, and distribution of

- Dental Materials
 - Abutments
 - Accessories for the use of dental materials
 - Accessories for the use of preformed complete removable dentures
 - Accessories for ceramic materials for fixed prostheses (colouring liquids)
 - Artificial teeth
 - Bite registration materials
 - Cavity lining materials
 - Ceramic, polymer- and metal based materials for fixed prostheses (crowns, bridges, inlays, onlays, veneers)
 - Core Build-up materials
 - Dentine and enamel adhesives
 - Endodontic filling materials
 - Impression materials
 - Luting materials (cements, polymers)
 - Materials for removable prostheses (polymers)
 - Materials for surface preparation (etch, prime)
 - Materials for the fabrication of occlusal splints, drilling templates, impression trays, bite templates, bleaching splints
 - Materials for the protection of the pulp and for periodontal use
 - Pit and fissure sealants
 - Plastic materials for direct insertion (polymers, cements, metals)
 - Preformed complete removable dentures (polymers)
 - Relining materials
 - Temporary crown and bridge-, inlay- and onlay materials
 - Temporary luting materials (cements)
 - Waxes
- Disinfectants
- Detergents for medical instruments
- Examination gloves

Sites covered by this certificate

MERZ DENTAL GmbH, Kieferweg 1, 24321 Lütjenburg, Germany
Facility ID: F006037

Site-specific scope

Design and development, manufacture, final inspection, and distribution of

- Dental Materials
 - Abutments
 - Accessories for the use of dental materials
 - Accessories for the use of preformed complete removable dentures
 - Accessories for ceramic materials for fixed prostheses (colouring liquids)
 - Artificial teeth
 - Bite registration materials
 - Cavity lining materials
 - Ceramic, polymer- and metal based materials for fixed prostheses (crowns, bridges, inlays, onlays, veneers)
 - Core Build-up materials
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- Waxes
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