



MANAGEMENT SYSTEM CERTIFICATE

Certificate no.
0439GB451260826

Final assessment report no.
0439AU36F

Effective date
2026-09-01

Expiry date
2029-08-31

This is to certify that

MERZ DENTAL GmbH

Kieferweg 1, 24321 Lütjenburg, Germany

has introduced, applies and maintains a management system at the site(s) listed on the following page(s).

This management system has been audited and found to conform to the quality management systems standard

ISO 13485:2016 and the following country-specific requirements

Australia:	Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) / Part 4
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 – Subparts A to D; 21 CFR 820; 21 CFR 821 (where applicable)

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

Place and date
Hamburg, 2026-08-26

For the issuing office
DNV MEDCERT GmbH
Brooktorkai 18, 20457 Hamburg, Germany



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

Dr Ralf Reimer-Guénou
Certification Body Operations

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

820114 EN Rev 8 2026.06.29

MDSAP RECOGNIZED AUDITING ORGANIZATION: DNV MEDCERT GmbH
Brooktorkai 18, 20457 Hamburg, Germany, Tel +49 40 2263325-0, www.dnv.com

Activities and products/services covered by this certificate

Design and development, manufacturing, 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 and associated (partial) scopes

MERZ DENTAL GmbH, Kieferweg 1, 24321 Lütjenburg, Germany

Facility ID: F006037

Design and development, manufacturing, and distribution of

- Dental Materials
 - Abutments
 - Accessories for the use of dental materials
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