

## MANAGEMENT SYSTEM CERTIFICATE

Certificate no. 0439GB445230307 Final assessment report no.

Effective date

Expiry date 2025-09-13

This is to certify that

## MERZ DENTAL GmbH

Kieferweg 1, 24321 Lütjenburg, Germany

Has introduced, applies, and maintains a management system at the sites listed on the following pages.

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

EN ISO 13485:2016

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

Markus Biar chi Director Certification Body



Certificate no.: 0439GB445230307 Place and date: Hamburg, 2023-03-07

## Sites covered by this certificate

MERZ DENTAL GmbH, Kieferweg 1, 24321 Lütjenburg, Germany

## Activities and products/services covered by this certificate

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
  - 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