

# MANAGEMENT SYSTEM CERTIFICATE

Certificate no. 2338GB445231005 Final assessment report no.

Effective date 2023-10-05

Expiry date 2026-08-07

This is to certify that

## **Dental Direkt GmbH**

Industriezentrum 106 - 108, 32139 Spenge, 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, 2023-10-05



Deutsche Akkreditierungsstelle D-ZM-19630-04-00 For the issuing office
DNV MEDCERT GmbH
Pilatuspool 2, 20355 Hamburg, Germany

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 Medcert-12info@dnv.com

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Certificate no.: 2338GB445231005 Place and date: Hamburg, 2023-10-05

### Sites covered by this certificate

Dental Direkt GmbH, Industriezentrum 106 - 108, 32139 Spenge, Germany Dental Direkt GmbH, Industriezentrum 11, 32139 Spenge, Germany Dental Direkt GmbH, St.-Annener Str. 119, 49326 Melle, Germany

#### Activities and products/services covered by this certificate

Design and development, manufacture, final inspection and distribution of

- Dental materials
  - Ceramic, polymer and metal materials for fixed prostheses (crowns, bridges, inlays, onlays, veneers)
  - Materials for removable prostheses (polymers, metals)
  - Accessories for ceramic materials for fixed prostheses (colouring liquids, veneering ceramics)
  - Temporary crown and bridge materials (polymers)
  - Materials for the fabrication of occlusal splints, drilling templates, bite templates
  - Accessories for implants (abutments, titanium bonding bases, titanium screws, scanbodies)

#### Purchase and distribution of

- Dentistry products
- Devices for dental laboratories