



MANAGEMENT SYSTEM CERTIFICATE

Certificate no
2338GB452251218

Final assessment report no.
2338AU30F

Effective date
2025-12-18

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 page(s).

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

EN ISO 13485:2016 + AC:2018 + A11:2021

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

Place and date
Hamburg, 2025-12-18

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



DAkkS

Deutsche
Akkreditierungsstelle
D-ZM-19630-04-00


Annika Chill
Certification Body Operations

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

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

CERTIFICATION BODY: DNV MEDCERT GmbH
Pilatuspool 2, 20355 Hamburg, Germany, Tel +49 40 2263325-0, www.dnv.com

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Activities and products/services covered by this certificate

Design and development, manufacturing, and distribution of

- Dental materials
 - Materials for fixed prostheses (ceramics, polymers, metals)
 - Materials for removable prostheses (polymers, metals)
 - Accessories for ceramic materials for fixed prostheses (colouring liquids, veneering ceramics)
 - Materials for temporary crowns and bridges (polymers)
 - Materials for the fabrication of occlusal splints, drilling templates, bite templates
 - Accessories for implants (abutments, titanium bonding bases, titanium screws, scanbodies)

Distribution of

- Dentistry products
- Devices for dental laboratories

Sites covered by this certificate and associated (partial) scopes

Dental Direkt GmbH, Industriezentrum 106-108, 32139 Spenge, Germany

Design and development of

- Dental materials
 - Materials for fixed prostheses (ceramics, polymers)
 - Materials for removable prostheses (polymers)
 - Accessories for ceramic materials for fixed prostheses (colouring liquids, veneering ceramics)
 - Materials for temporary crowns and bridges (polymers)
 - Materials for the fabrication of occlusal splints, drilling templates, bite templates
 - Accessories for implants (abutments, titanium bonding bases, titanium screws, scanbodies)

Manufacturing of

- Dental materials
 - Materials for fixed prostheses (ceramics)
 - Accessories for ceramic materials for fixed prostheses (colouring liquids, veneering ceramics)

Distribution of

- Dental materials
 - Materials for fixed prostheses (ceramics, polymers, metals)
 - Materials for removable prostheses (polymers, metals)
 - Accessories for ceramic materials for fixed prostheses (colouring liquids, veneering ceramics)
 - Materials for temporary crowns and bridges (polymers)
 - Materials for the fabrication of occlusal splints, drilling templates, bite templates
 - Accessories for implants (abutments, titanium bonding bases, titanium screws, scanbodies)
- Dentistry products
- Devices for dental laboratories

Dental Direkt GmbH, St.-Annener-Str. 119, 49326 Melle, Germany

Manufacturing of

- Dental materials
 - Materials for fixed prostheses (polymers)
 - Materials for removable prostheses (polymers)
 - Materials for temporary crowns and bridges (polymers)
 - Materials for the fabrication of occlusal splints, drilling templates, bite templates
 - Accessories for implants (abutments, titanium bonding bases, titanium screws, scanbodies)

Distribution of

- Dentistry products
- Devices for dental laboratories



Certificate no.: 2338GB452251218
Place and date: Hamburg, 2025-12-18

Dental Direkt GmbH, Industriezentrum 11, 32139 Spenge, Germany
Distribution of

- Dental materials
 - Materials for fixed prostheses (ceramics, polymers, metals)
 - Materials for removable prostheses (polymers, metals)
 - Accessories for ceramic materials for fixed prostheses (colouring liquids, veneering ceramics)
 - Materials for temporary crowns and bridges (polymers)
 - Materials for the fabrication of occlusal splints, drilling templates, bite templates
 - Accessories for implants (abutments, titanium bonding bases, titanium screws, scanbodies)
- Dentistry products
- Devices for dental laboratories

