



# MANAGEMENT SYSTEM CERTIFICATE

Certificate no.  
2338GB451231030

Final assessment report no.  
2338AU28F

Effective date  
2023-10-30

Expiry date  
2026-08-07

This is to certify that the management system of  
**Dental Direkt GmbH**  
Industriezentrum 106-108, 32139 Spenge, Germany  
Facility ID: F006026  
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, 2023-10-30

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  
Medcert-info@dnv.com

## Activities and products/services covered by this certificate

Design and development, manufacture 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)



## Sites covered by this certificate

Dental Direkt GmbH, Industriezentrum 106-108, 32139 Spenge, Germany  
Facility ID: F006026

### Site-specific scope

#### 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)

#### Manufacture 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)

Dental Direkt GmbH - Fräs- und Technologiezentrum, St.-Annener Str. 119, 49326 Melle, Germany  
Facility ID: F006026

### Site-specific scope

#### Manufacture 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)

Dental Direkt GmbH, Industriezentrum 11, 32139 Spenge, Germany  
Facility ID: F006026

### Site-specific scope

#### Distribution of

- Dental materials