



MANAGEMENT SYSTEM CERTIFICATE

Certificate no.
2338GB451230227

Final assessment report no.
2338SA26F

Effective date
2023-02-27

Expiry date
2023-08-07

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, 2023-02-27

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

DNV MEDCERT is an MDSAP
authorised auditing organisation

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

Markus Bianchi
Director Certification Body

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

820114 EN Rev 5 2022.11.16

AUTHORISED UNIT: DNV MEDCERT GmbH (previously: MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH)
Pilatuspool 2, 20355 Hamburg, Germany, Tel +49 40 2263325-0, www.med-cert.com, www.dnv.com



Certificate no.: 2338GB451230227
Place and date: Hamburg, 2023-02-27

Activities and products/services covered by this certificate

Design and development, manufacture, 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)

Sites covered by this certificate

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

Site-specific scope

Design and development, manufacture, 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)

Dental Direkt GmbH - Fräs- und Technologiezentrum, St.-Annener Str. 119, 46326 Melle, Germany
Facility ID: F006026

Site-specific scope

Design and development, manufacture, and distribution of

- Dental materials
 - Accessories for implants (abutments, titanium bonding bases, titanium screws, scanbodies)