MED CERT®

Certification. Medical Only.

EC Certificate of Conformity

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith certifies that the company:

Dental Direkt GmbH
Industriezentrum 106 - 108
32139 Spenge
Germany

with locations listed in the appendix

has introduced, applies and maintains a quality assurance system for the products / product categories listed in the appendix.

The compliance of this quality assurance system with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex II without section 4

This certification is subject to surveillance by MEDCERT.

Effective date: **2021-05-24**
Expiry date: **2024-05-27**

Report No.: 2338FS24F
Process No.: QS – 2338
Certificate No.: 2338GB410210524A

Hamburg, 2021-05-24

MEDCERT Certification Body
(Dr. Andreas Schich)

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

MEDCERT Identification Number: 0482

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Appendix of EC Certificate of Conformity

Process No.: QS – 2338
Certificate No.: 2338GB410210524A

List of locations included in the scope of certificate

St. Annener Str. 119
49326 Melle
Germany

– End of list –

This appendix is integral part of the above-referenced certificate.
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Appendix of EC Certificate of Conformity

Process No.: QS – 2338
Certificate No.: 2338GB410210524A

List of products / product categories included in the scope of certificate

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**
- **Accessories for implants (abutments, titanium bonding bases, titanium screws)**

– End of list –

Dental Direkt GmbH
Industriezentrum 106 - 108
DE 32139 Spenge
Germany

DNV MEDCERT GmbH
Pilatuspool 2
20355 Hamburg
Germany

Tel: +49 40 2263325-0
E-mail: Medcert-Info@dnv.com

Date:	**Our reference**:	**Your reference**:
2023-10-05	QS-2338	

Confirmation letter correcting and complementing information on an existing certificate in accordance with Article 120 (3) of Regulation (EU) 2017/745

Directive and annex	**Directive 93/42/EEC, Annex II**
Organisation	**Dental Direkt GmbH**
Registered place of business	Industriezentrum 106 - 108 32139 Spenge Germany
Certificate number	2338GB410210524A
Certificate expiry date	2024-05-27
Scope of certification	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 • Accessories for implants (abutments, titanium bonding bases, titanium screws)
Description of change(s)	addition of an additional facility location: Dental Direkt GmbH Industriezentrum 11 32139 Spenge

Effective date of change(s) 2023-10-05

To whom it may concern,

DNV MEDCERT GmbH (previously: MEDCERT Prüfungs- und Zertifizierungsgesellschaft für die Medizin GmbH), a Notified Body according to Regulation (EU) 2017/745 on medical devices (MDR)[1] (NB 0482), herewith declares that, pursuant to Article 120 (1) of MDR, since 26 May 2021, no certificate under the Directive 93/42/EEC (Medical Device Directive, or MDD)[2] is allowed to be issued any more.

Consequently, pursuant to guidance MDCG 2020-3[3], this Confirmation Letter is valid together with and complements the above-referenced certificate. We as a Notified Body are continuing to perform the surveillance activities for MDD certificates issued by DNV MEDCERT which are still valid, as laid out in the Article 120 (3) of MDR.

We hereby confirm that the above-referenced certificate has been issued to the above-referenced manufacturer and is still valid with the change(s) described in this letter.

We hereby confirm that the aforementioned change(s) is (are) not considered significant change(s) to the design and/or intended purpose as described in Article 120 (3) of MDR. The evaluation of documents related to the change(s) has been completed and approved.

Hamburg, 2023-10-05

Markus Bianchi
Director Certification Body

[1] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (http://data.europa.eu/eli/reg/2017/745/2020-04-24).
[2] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (http://data.europa.eu/eli/dir/1993/42/2007-10-11).
[3] MDCG 2020-3 Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD (available on https://ec.europa.eu/health/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en).