

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:

MERZ DENTAL GmbH
Kieferweg 1
24321 Lütjenburg
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: 2019-12-05
Expiry date: 2024-05-27

Report No.: QS-0439FS28F
Process No.: QS – 0439
Certificate No.: 0439GB410191205

Hamburg, 2019-12-05


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.

MEDCERT Identification Number: 0482

Form F10010005e EN / Rev. 11 / 2019.11.14



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

Appendix of EC Certificate of Conformity

Process No.: QS – 0439
Certificate No.: 0439GB410191205

List of locations included in the scope of certificate

MERZ DENTAL GmbH
Eetzweg 20
24321 Lütjenburg
Germany

– End of list –

This appendix is integral part of the above-referenced certificate.
The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT Identification Number: 0482

Form F10010005e EN / Rev. 11 / 2019.11.14



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

Appendix of EC Certificate of Conformity

Process No.: QS – 0439

Certificate No.: 0439GB410191205

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

- **Dental materials**
 - **Abutments**
 - **Accessories for ceramic materials for fixed prostheses (colouring liquids)**
 - **Artificial teeth**
 - **Cavity lining materials**
 - **Ceramic, polymer- and metal materials for fixed prostheses (crowns, bridges, inlays, onlays, veneers)**
 - **Core build-up materials**
 - **Dentine and enamel adhesives**
 - **Endodontic filling materials**
 - **Luting materials (cements, polymers)**
 - **Materials for removable prostheses (polymers)**
 - **Materials for surface preparation (etch, prime)**
 - **Materials for the fabrication of occlusal splints and drilling templates (polymers)**
 - **Materials for the protection of the pulp and for periodontal use**
 - **Pit and fissure sealants**
 - **Plastic materials for direct insertion (polymers, cements, metals)**
 - **Preformed complete removable dentures (polymers)**
 - **Relining materials**
 - **Temporary crown and bridge-, inlay- and onlay materials**
 - **Temporary luting materials (cements)**

- **Disinfectants**

– End of list –

This appendix is integral part of the above-referenced certificate.
The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT Identification Number: 0482

Form F10010005e EN / Rev. 11 / 2019.11.14



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