

Certificate

The certification 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 management system in the area of:

**Design and development, manufacture, final inspection and distribution
of products as listed in the appendix**

Manufacture and final inspection of dental ceramics based on feldspar

The conformity of this quality management system to the requirements of the below mentioned standard was verified by an audit:

EN ISO 13485:2016

This certification is subject to surveillance by MEDCERT.

Effective date: 2019-12-05

Expiry date: 2022-09-13

Report No.: 0439FS28F

Procedure No.: QS – 0439

Certificate No.: 0439GB445191205

Hamburg, 2019-12-05



MEDCERT Certification Body
(Dr. Andreas Schich)

The certificate is only valid when provided entirely with all of its pages.
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D-ZM-19630-04-00

Appendix of certificate

Procedure No.: QS – 0439

Certificate No.: 0439GB445191205

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.
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Appendix of certificate

Procedure No.: QS – 0439

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List of products included in the scope of certificate

- **Dental materials**
 - **Abutments**
 - **Accessories for the use of dental materials**
 - **Accessories for the use of preformed complete removable dentures**
 - **Accessories for ceramic materials for fixed prostheses (colouring liquids)**
 - **Artificial teeth**
 - **Bite registration materials**
 - **Cavity lining materials**
 - **Ceramic, polymer- and metal based materials for fixed prostheses (crowns, bridges, inlays, onlays, veneers)**
 - **Core Build-up materials**
 - **Dentine and enamel adhesives**
 - **Endodontic filling materials**
 - **Impression materials**
 - **Luting materials (cements, polymers)**
 - **Materials for removable prostheses (polymers)**
 - **Materials for surface preparation (etch, prime)**
 - **Materials for the fabrication of occlusal splints, drilling templates, impression trays, bite templates, bleaching splints**
 - **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)**
 - **Waxes**
- **Disinfectants**
- **Detergents for medical instruments**
- **Examination gloves**

– End of list –

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