

Certificate

The Certification Body

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

herewith certifies that the company

**S&C Polymer Silicon und Composite Spezialitäten GmbH
Robert-Bosch Str. 2
25335 Elmshorn
Germany**

has introduced, applies and maintains a quality management system in the area of activities, products/services and locations listed in the appendix.

The conformity of this quality management system to the requirements of the following standard and country-specific requirements of the following jurisdictions¹ has been verified by an audit:

**ISO 13485:2016
Canada, United States of America**

This certification is subject to surveillance by MEDCERT.

**Effective date: 2021-12-16
Expiry date: 2023-05-07**

Report No.: 0359SA30F
Procedure No.: QS – 0359
Certificate No.: 0359GB451211216

Hamburg, 2021-12-16

MEDCERT Certification Body
Markus Bianchi

¹ Individual country-specific requirements are listed in the appendix.

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 is an MDSAP authorised auditing organisation.

Appendix of certificate

Procedure No.: QS – 0359

Certificate No.: 0359GB451211216

Activities and products/services in the scope of certification

Design, manufacturing, final inspection, and distribution of dental materials

- Impression trays
- Impression materials
- Luting materials (cements, polymers)
- Bite registration materials
- Bleaching agents for internal and external dental bleaching (professional dental use only)
- Dentin- and enamel adhesives
- Endodontic filling materials
- Pit and fissure sealants
- Filling cements
- Conditioning agents
- Plastic materials for direct insertion (polymers)
- Prophylaxis materials
- Temporary filling materials
- Temporary crown and bridge materials
- Pulp capping materials
- Retraction materials
- Protective films
- Core build-up materials
- Cavity lining materials
- Relining materials
- Waxes
- Materials for fixed prosthesis (polymers)
- Materials for removable dentures (polymers)
- Materials for surface preparation (etch, prime)
- Accessories for the use of dental materials
- Otoplastic and podoplastic materials

Country-specific requirements implemented in the quality management system

Canada – Medical Devices Regulations SOR/98-282, Part 1 (applicable requirements)

United States of America – 21 CFR 803; 21 CFR 806; 21 CFR 807 (Subparts A to D); 21 CFR 820

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Locations in the scope of certification**S&C Polymer Silicon und Composite Spezialitäten GmbH****Robert-Bosch Str. 2****25335 Elmshorn****Germany**

Facility ID: F005698

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