SZUTEST
Konformitätsbewertungsstelle GmbH

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

According to Annex IX-Chapters I and III of the Regulation (EU) 2017/745 on Medical Devices

Certificate No.: 2975-MED-2616701

Manufacturer:	**SLH Microtech GmbH** Tiergartenstr. 7b, 64646 Heppenheim (Bergstr.), Germany
Manufacturer's SRN:	DE-MF-000020864
Device Information:	**See Section 2**
Report No.:	MD0178-P002-R01
Specific Conditions or Limitations:	N/A
Revision History:	**See Section 3**

SZUTEST Konformitätsbewertungsstelle GmbH, Notified Body 2975, declares that the aforementioned manufacturer has implemented a quality management system according to Annex IX Chapters I and III of the Regulation (EU) 2017/745 on medical devices. This quality system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Regulation. The approved quality system is subject to surveillance pursuant to Annex IX Chapter I Section 3 of the Regulation and unannounced site audits.

The Report(s) stated above summarize the conformity assessment results and include references to the relevant CS, harmonized standards, sampled/reviewed technical documentation, and test reports.

SZUTEST Konformitätsbewertungsstelle GmbH must be informed of any substantial changes in the design and/or construction of the device(s).

For placing on the market class III devices and class IIb devices referred to in the second subparagraph of Article 52(4) covered by this certificate, an EU Technical Documentation Assessment certificate according to Annex IX Chapter II is required.

First Issue Date:	16-06-2026
Revision Date:	16-06-2026
Revision No.:	00
Validity Date:	15-06-2031

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-089

Mehmet IŞIKLAR
General Manager

This certificate can be validated by scanning the QR code or entering necessary information at https://public.szutest-germany.de/

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Section 2 – Device Information

No	Device(s) / Device Group(s)	Model(s)	Basic UDI-DI	Risk Class	Intended Purpose
1	**Sterile DCX Dental Implants**	DCX Bone Level Dental Implant	426066223DCXEC	IIb	SLH DCX Bone Level Dental Implants are surgically placed into the upper or lower jawbone to support artificial dental prostheses, thereby restoring the patient's chewing function. SLH DC Covers are temporarily placed over dental implants to prevent leakage.
2	**Non-sterile DC Dental Superstructures**	Standard Straight Abutment	426066223SSAGR	IIb	SLH DC Dental Superstructures are intended for permanent use in the upper and/or lower jaw in conjunction with SLH DCX dental implants to provide support for crowns, bridges, or dentures in edentulous or partially edentulous patients.
		Universal Straight Abutment	426066223USAH3		
		Esthetic Straight Abutment	426066223ESAEK		
		Angled Abutment	426066223AANX		
		Esthetic Angled Abutment	426066223EAACV		
		Multiunit Abutment	426066223MAQ3		
		Ball Abutment	426066223BAP2		
		Universal Ti-Base Casting Abutment	426066223TCAFE		
		Cad-Cam Ti-Base Abutment	426066223CTAEC		
		Cad-Cam Cerec Ti-Base Abutment	426066223CCTA66		
		Equator Abutment	426066223EAACV		
		Multi-Unit Tibase Abutment	426066223MTAFW		
		Temporary Abutment	426066223TAQQ		SLH DC Dental Superstructures are intended for temporary use (3 months) in the upper and/or lower jaw in conjunction with SLH DCX dental implants to provide support for crowns, bridges, or dentures in edentulous or partially edentulous patients.
		Temporary Multi-Unit Abutment	426066223TMAGC		
		Screw	426066223SCQR		The abutment is used to attach to the implant, providing a connection between the implant and the abutment.
		Gingiva Former	426066223GFPT		SLH DC Gingiva formers are designed to allow soft tissue (gum) shaping after dental implant surgery and to provide a temporary intermediate fixture level between the dental implant and the temporary dental prosthesis.
		Temporary Gingiva Former	426066223TGFG4		
		Comfort Cap	426066223CAPDH		It prevents any substance from entering into the abutment during the osteointegration process or the prosthesis construction process. Comfort Caps are used with multi-unit abutments.
		Sinus Cover	426066223SCVGK		The sinus cover is used to cover the implant after it has been placed in the bone and to prevent the implants from moving towards the sinus.

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Section 3 – Revision History

Revision No	Revision Date	Identification of changes / definitions
00	16-06-2026	Initial Certification.