

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-2529701

Manufacturer: ŞANLILAR TIBBİ CİHAZLAR MEDİKAL KİMYA SANAYİ VE
TİCARET LİMİTED ŞİRKETİ
İTOB OSB Mah. İTOB Atatürk Cad. No: 24 Tekeli,
Menderes/Izmir/TÜRKİYE

Manufacturer's SRN: TR-MF-000014938

Device Information: See Section 2

Report No.: MD0005-P001-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: 24-10-2025
Revision Date: 24-10-2025
Revision No.: 00
Validity Date: 23-10-2030



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
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Mehmet IŞIKLAR
General Manager

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Section 2 – Device Information

No	Device(s) / Device Group(s)	Model(s)	Basic UDI-DI	Risk Class	Intended Purpose
1	Non-Sterile T6 & T6 Torq Surgical Instruments	Point Drill, Round Drill, Drill Extension, Countersink, Pilot Drill, Final Drill, Hard Bone Drill, Short Implant Drill, Screw Retrieval Drill, Trephine Drill, Bone Condenser	8699383353J3	IIa	Surgical instruments are used to prepare implant sites, placement in the bone of the upper or lower jaw for NucleOSS Dental Implants, to insert the implants in the sites, to tighten and unscrew all the fixation screws.
2	Non-Sterile T6 & T6 Torq Surgical Sets	CRH-109 Plastic Stopper Surgical Set, CRH-110 T6 Fix on 4 Surgical Set, CRH-111 Easy Surgical Guide Kit, CRH-113 Metric Screw Retrieval Kit, CRH-115 Plastic Stopper Surgical Set, CRH-116 T6 & T6 TORQ Plastic Stopper Surgical Set	8699383352HZ		

No	Device(s) / Device Group(s)	Model(s)	Basic UDI-DI	Risk Class	Intended Purpose
3	Sterile T6 & T6 Torq Dental Implants	T6	869938335T67A	IIb	Dental Implants are medical devices that intended to be surgically placed in the bone of the maxillary and/or mandibular arches to provide support for prosthetic restorations in edentulous or partially edentulous patients, such as artificial teeth, to restore a patients' chewing function.
		T6 Torq	869938335TRQ43		

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4	Non Sterile T6 & T6 TORQ Dental Superstructures	Standard Straight Abutment	869938335SSA2Z	IIb	Superstructures are intended for use with NucleOSS Dental Implants in the maxillary and/or mandibular arches to provide support for crowns, bridges, or overdentures for edentulous or partially edentulous patients.
		Universal Straight Abutment	869938335USA3B		
		Esthetic Straight Abutment	869938335ESAYQ		
		Angled Abutment	869938335AA65		
		Esthetic Angled Abutment	869938335EAAX2		
		Multiunit Abutment	869938335MA79		
		Ball Abutment	869938335BA68		
		Universal Ti-Base Casting Abutment	869938335TCAZK		
		Cad-Cam Ti-Base Abutment	869938335CTAYH		
		Cad-Cam Cerec Ti-Base Abutment	869938335CCTATM		
		Equator Abutment	869938335EA6H		
		Temporary Abutment	869938335TA7W		
		Gingiva Former	869938335GF6Z		
		Screw	869938335SR8V		
		Temporary Gingiva Former	869938335TGF2C		
		Premil Abutment	869938335PA7J		
		Temporary Multi-Unit Abutment	869938335TMA2L		
		Multi-Unit Tibase Abutment	869938335MTA26		
		CoCr Casting Abutment	869938335CCAWW		

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Certificate No.: 2975-MED-2529701

Section 3 – Revision History

Revision No	Revision Date	Identification of changes / definitions
00	24-10-2025	Initial Certification.

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-2529702

Manufacturer: ŞANLILAR TIBBİ CİHAZLAR MEDİKAL KİMYA SANAYİ VE
TİCARET LİMİTED ŞİRKETİ
İTOB OSB Mah. İTOB Atatürk Cad. No: 24 Tekeli,
Menderes/Izmir/TÜRKİYE

Manufacturer's SRN: TR-MF-000014938

Device Information: See Section 2

Report No.: MD0005-P001-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 mentioned device(s).

The quality management system evaluation is restricted,

For Class I devices in sterile conditions, to the aspects of manufacture concerned with securing and maintaining sterile conditions,

For Class I devices with a measuring function, to the aspects of manufacture concerned with the conformity of the devices with metrological requirements

For Class I reusable surgical instruments, to the aspects of cleaning, disinfection, sterilization, maintenance and functional testing.

For Sterile Systems or Sterile Procedure Packs, to aspects of the sterilization procedure for ensuring sterility until the sterile package is opened or damaged.

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Certificate No.: 2975-MED-2529702

Section 2 – Device Information

No	Device(s)/Device Group	Basic UDI-DI	Risk Class
1	Surgical Instruments (Measuring) Torque Ratchet, Depth Gauge, Multi-Unit Planning Template for Angulation	869938335C1mXR	Im
2	Surgical Instruments (Reusable) Parallel Pin, Profile Cover, Hand Tool, Hex Driver, Transport-Tightening Part, Ratchet Motor Adapter	869938335C1rY3	Ir
3	Surgical Instrument Set CRH-108 T6 Prosthetic Kit	869938335IRS2G	Ir

Section 3 – Revision History

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