



**SZUTEST**  
NOTIFIED BODY 2195

## EC CERTIFICATE AT SERTİFİKA

According to Annex II of the Directive 93/42/EEC on Medical Devices

93/42/AT Tıbbi Cihaz, Yönetmeliği Ek II'ye göre

**Full Quality Assurance System**  
Tam Kalite Güvencesi

**Certificate Number: 2195-MED-1329801**  
Sertifika Numarası

**Manufacturer:**  
Üretici

**TIPSAN TIBBİ ALETLER SAN. VE TİC. A.Ş.**  
Kemalpaşa Cad. 7404/1 Sok. No:3 Pınarbaşı/ İZMİR/ TURKEY

**Product(s):**  
Ürün(ler)

**Orthopaedic Implants**  
Ortopedik İmplantlar

**Model(s)**  
Model(ler)

**Specification of Products is stated on 2<sup>nd</sup> - 5<sup>th</sup> pages**  
(Ürün çeşitleri 2-5. sayfalarda verilmiştir).

**Brand Name(s):**  
Marka(lar)

**TIPSAN**

**Final Report No:**  
Final Raporu Numarası

**2195-MED-1310004, 2195-MED-1404003 Rev.01, 2195-MED-1405010, 2195-MED-1406011,  
2195-MED-1406016**

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II, Section 3 of the directive 93/42/EEC on medical devices. This quality assurance 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 Directive. The approved quality system is subject to surveillance pursuant to Annex II, Section 5 of Directive 93/42/EEC and unannounced audits. Szutest must be informed of any significant changes in the design and/or construction of the product(s).

2195 kimlik numaralı Onaylanmış Kuruluş Szutest, yukarıda belirtilen üreticinin 93/42/AT Tıbbi Cihaz Yönetmeliği EK II, madde 3'e göre bir kalite yönetim sistemi uyguladığını, bu yönetim sisteminin yönetmeliğin sadece bahsi geçen ürünün üretiminin güvenlik koşullarını sağlama ve devam ettirme ile ilgili gerekliliklerin karşıladığını beyan eder. Onaylanan bu kalite yönetim sistemi, 93/42/AT Tıbbi Cihaz Yönetmeliği EK II, Madde 5'e göre periyodik olarak gözetime ve habersiz saha denetimlerine tabidir. Üretici, ürünlerinin tasarımında ve yapısında gerçekleştirdiği önemli değişiklikleri Szutest'e bildirmek zorundadır.

**This EC certificate is valid till 2018-10-24**  
**Bu AT Sertifikası tarihine kadar 2018-10-24 geçerlidir.**

Istanbul, 2013-10-25  
Rev.05, 2015-02-12



Özgür Vicdan  
Deputy General Manager  
Genel Müdür Yardımcısı.







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**Certificate Number: 2195-MED-1329801**

*Sertifika Numarası*

**Product Specification:**

**Ürün Detayları**

**Zweymuller Modular Cementless Stem**  
*Zweymuller Modüler Çimentosuz Stem*

Zweymuller Modular Cementless Stem  
Zweymuller Modular Cementless Stem - HA Coated  
Zweymuller Modular Cementless Stem - Ti+HA Coated  
Zweymuller Modular Cementless Revision Stem  
Zweymuller Modular Cementless Revision Stem - HA Coated  
Zweymuller Modular Cementless Revision Stem - Ti+HA Coated

**PENTA MERS SYSTEM**

*Penta Mers Sistem*

**T2 HIP PROSTHESIS, UNCEMENTED**

*T2 Kalça Protezi, Çimentosuz*

T2 Hip Prosthesis Body  
T2 Hip Prosthesis Body with Adaptor  
T2 Hip Prosthesis Body Ti Coated  
T2 Hip Prosthesis Body HA Coated  
T2 Hip Prosthesis Body Ti+ HA Coated  
T2 Hip Prosthesis Neck, Straight  
T2 Hip Prosthesis Neck, Angled  
T2 Hip Prosthesis Fixation Bolt  
T2 Hip Prosthesis Anatomic Stem, Uncemented  
T2 Hip Prosthesis Stem, Uncemented  
T2 Hip Prosthesis Stem Ti Coated, Uncemented  
T2 Hip Prosthesis Stem HA Coated, Uncemented  
T2 Hip Prosthesis Stem Ti+HA Coated, Uncemented  
T2 Revision Hip Prosthesis Stem, Uncemented  
T2 Revision Hip Prosthesis Stem, Ti Coated, Uncemented  
T2 Revision Hip Prosthesis Stem HA Coated, Uncemented  
T2 Revision Hip Prosthesis Stem Ti+HA Coated, Uncemented

**CTPH MODULAR STRAIGHT STEM, UNCEMENTED**

*CTPH Modüler Düz Stem, Çimentosuz*

CTPH Modular Straight Stem With Ti+HA Coated, Uncemented

**CTD MODULAR STRAIGHT STEM, CEMENTED**

*CTD Modüler Düz Stem, Çimentolu*

**MODULAR BIPOLAR CUP, UNCEMENTED**

*Modüler Bipolar Kap, Çimentosuz*

**MODULAR HEADS**

*Modüler Kafalar*

**PRESS FIT CUP UNCEMENTED**

*Press Fit Kap, Çimentosuz*

Press Fit Cup - Uncemented - HA Coated  
Press Fit Cup - Uncemented - Polished  
Press Fit Cup - Uncemented - Ti Spray Coated  
Press Fit Cup - Uncemented - Ti+HA Coated  
Press Fit Cup - Uncemented  
Press Fit Cup Insert  
Starex Fixation Screw







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**Product Specification:**

*Ürün Detayları*

**T08 TOTAL KNEE SYSTEM**

*T08 Total Diz Sistemi*

T08 Tibial Component with Uncemented  
T08 Tibial Component with Ti+HA Coated, Uncemented  
T08 Tibial Component - Tin Coated with Uncemented  
T08 Tibial Component Half Spacer  
T08 Tibial Component Half Spacer Screw  
T08 Tibial Component Half Spacer - TiN Coated  
T08 Tibial Component with Ti+HA Coated, Uncemented

T08 Standard Femoral Component with Cemented  
T08 PS Femoral Component with Cemented  
T08 Standard Femoral Component with Ti+HA Coated, Uncemented  
T08 Standard Femoral Component with Dual Coated, Uncemented  
T08 PS Femoral Component with Ti+HA Coated, Uncemented  
T08 PS Femoral Component with Dual Coated, Uncemented  
T08 Standard Femoral Component - Tin Coated with Cemented  
T08 PS Femoral Component - Tin Coated with Cemented  
T08 Standard Femoral Component - Tin Coated with Uncemented  
T08 PS Femoral Component - Tin Coated with Uncemented

T08 Standard Tibial Insert  
T08 PS Tibial Insert  
T08 Tibial Insert Constrained  
T08 Standart Hyperflex Tibial Insert  
T08 PS Hyperflex Tibial Insert  
T08 Constrained Tibial Insert

T08 Patella Component  
T08 Re-Surfacing Patella Component

T08-MB Standart Deep Dish Tibial Insert  
T08-MB PS Deep Dish Tibial Insert

T08-MB Standart Tibial Insert  
T08-MB PS Tibial Insert  
T08-MB Constrained Tibial Insert  
T08-MB Standart Hyperflex Tibial Insert  
T08-MB PS Hyperflex Tibial Insert

T08-MB Tibial Component with Cemented  
T08-MB Tibial Component with Ti+HA Coated, Uncemented  
T08-MB Tibial Component - Tin Coated with Cemented  
T08-MB Tibial Component - Tin Coated with Uncemented  
T08-MB Tibial Component - Dual Coated with Uncemented  
T08-MB Tibial Component, Uncemented

T08-MB Patella Component  
T08-MB Re-Surfacing Patella Component

T08-MB Tibial Stem  
T08-MB Tibial Stem - Tin Coated  
T08-MB Tibial Stem - Ti+HA Coated

**TMK- 1 Modular Straight Stem, Cemented**

*TMK-1 Modüler Düz Stem, Çimentolu*

TMK-1 Modular Stem - Cemented - Polished

**TMK- 1 Modular Straight Stem, Uncemented**

*TMK-1 Modüler Düz Stem, Çimentosuz*

TMK-1 Modular Stem – Uncemented  
TMK-1 Modular Stem – Uncemented - Porous Coated  
TMK-1 Modular Stem – Uncemented - HA Coated  
TMK-1 Modular Stem – Uncemented - Porous+HA Coated  
TMK-1 Modular Stem  
TMK-1 Modular Stem – Uncemented - Plasma+HA Coated  
TMK-1 Modular Stem – Uncemented - Polished







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**Product Specification:**

*Ürün Detayları*

**Press Fit Cup with Ti+HA Coated**  
*Press Fit Kap, Ti + HA Kaplamalı*

**Ceramic Liner for Press Fit Cup with Ti + HA Coated**  
*Press Fit Kap için Seramik Liner, Ti + HA Kaplamalı*

**PE Liner for Press Fit Cup with Ti + HA Coated**  
*Press Fit Kap için PE Liner, Ti + HA Kaplamalı*

**Modular Straight Stem, Uncemented**  
*Modüler Düz Stem, Çimentosuz*

**Modular Straight Stem, Cemented**  
*Modüler Düz Stem, Çimentolu*

**Modular Long Straight Stem, Cemented**  
*Modüler Uzun Düz Stem, Çimentolu*

**Acetabular Cup, Cemented**  
*Asetabular Kap, Çimentolu*

**Unipolar Heads**  
*Unipolar Kafalar*

Unipolar Head for Partial Prosthesis  
Unipolar Head for Partial Prosthesis with Cone Adaptor  
Cone Length Adaptor with Unipolar Head

**TMC-3 Modular Hip Prosthesis, Cemented**  
*TMC-3 Modüler Kalça Protezi, Çimentolu*

**TMC-4 Modular Hip Prosthesis with Collar, Cemented**  
*TMC-4 Modüler Kalça Protezi Yakalıklı, Çimentolu*

Cement Plug  
Stem Centralizer

**Thompson Hip Prosthesis**  
*Thompson Kalça Protezi*

**TAU-1 Anatomical Modular Stem, Cemented**  
*TAU-1 Anatomik Modüler, Çimentolu*

**TAU-2 Anatomical Modular Stem, Uncemented**  
*TAU-2 Anatomik Modüler Stem, Çimentosuz*

**Revision Stem, Uncemented**  
*Revizyon Stem, Çimentosuz*

**Reinforcement Cage, Uncemented**  
*Kuvvetlendirici Kafes, Çimentosuz*

**Modular Straight Stem, Uncemented**  
*Modüler Düz Stem, Çimentosuz*

Modular Straight Stem-Uncemented  
Modular Straight Stem-Uncemented-HA Coated

**Moore Hip Prosthesis**  
*Moore Kalça Protezi*

Moore Hip Prosthesis, Standard  
Moore Hip Prosthesis, Solid Stem  
Moore Hip Prosthesis, Narrow Stem  
Moore Hip Prosthesis, Narrow & Sold Stem







# SZUTEST®

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Certificate Number: 2195-MED-1329801

Sertifika Numarası

## Product Specification:

### Ürün Detayları

#### Modular Shoulder Prosthesis

##### Modüler Omuz Protezi

Modular Shoulder Prosthesis Cemented

Modular Head – Standard for Modular Shoulder Prosthesis Cemented

Modular Head – Eccentric for Modular Shoulder Prosthesis Cemented

Modular Head - 10° for Modular Shoulder Prosthesis Cemented

Modular Head – 15° for Modular Shoulder Prosthesis Cemented

Modular Head – High for Modular Shoulder Prosthesis Cemented

Glenoid Shell

Glenoid Insert

#### Acetabular Ring, Uncemented

##### Asetabular Halka, Çimentosuz

#### Bone Plates and Screws

##### Kemik Plakları ve Vidalar

#### Orthopaedic Internal Fixation, Spinal

##### Ortopedik Internal Fiksasyon, Spinal

#### Orthopaedic External Fixation Systems

##### Ortopedik Harici Fiksasyon Sistemi

#### Bone Nails

##### Kemik Çivileri

#### Bone Staples

##### Kemik U Çivileri

#### Bone Pins

##### Kemik Pinleri

#### Bone Wires

##### Kemik Telleri

