

EC CERTIFICATE

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

Full Quality Assurance System

Certificate Number: 2195-MED-38142001

Manufacturer: EUROMED IMPLANTS GmbH
Wilhadikirchhof 13 D-21682 Stade –Innenstadt /Germany

Product(s): Sterile and Non Sterile Orthopaedic Implants

Model(s): Product specification is stated on the previous pages.

Reference Report No: 2195-MED-1408009

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II, Section 3 and Section 4 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).

This EC certificate is valid till 2018-10-24.

Issue Date: 2014-08-28
Revision No.: 02 Rev.
Revision Date: 2017-11-22



Rukiye BALKAN
Deputy General Manager

SZUTEST

Certificate Number: 2195-MED-38142001

Product Specification:

Sterile QUADROFIT Total Knee System

QUADROFIT Standard Cemented Femoral Component
QUADROFIT Posterior Stabilized Cemented Femoral Component
QUADROFIT Standard Cementless Femoral Component
QUADROFIT Posterior Stabilized Cementless Femoral Component
QUADROFIT Standard Tibial Insert
QUADROFIT Standard Cemented Tibial Component
QUADROFIT Standard Cementless Tibial Component - Ti+Ha Coated
QUADROFIT Posterior Stabilized Tibial Insert
QUADROFIT Insert Patella Component
QUADROFIT Resurfacing Patella Component
QUADROFIT MB Standard Tibial Insert
QUADROFIT MB Posterior Stabilized Tibial Insert
QUADROFIT MB Cemented Tibial Component
QUADROFIT MB Cementless Tibial Component - Ti+HA Coated
QUADROFIT MB Cemented Tibial Component - TiN Coated
QUADROFIT MB Cementless Tibial Component - TiN Coated
QUADROFIT MB Tibial Stem
QUADROFIT MB Tibial Stem - TiN Coated

Sterile Cemented Cup

Sterile EMC Calcar Replacement Stem

EMC Calcar Replacement Cemented Stem

Sterile Modular Straight Stem - Modular Long Straight Stem

Modular Straight Cemented Stem
Modular Straight Cementless Stem

Sterile Optifit Cementless Cup

Sterile Zweymuller Modular Cementless 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

Sterile Almond Modular Stem

Almond Modular Cemented Stem
Almond Modular Cementless Stem

Sterile Ball Head

Sterile Bipolar Head



SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.

Szutest Plaza Nato Yolu Cad. Çam Sok. No:7 Ümraniye 34775 İSTANBUL / TÜRKİYE

SZUTEST

Certificate Number: 2195-MED-38142001

Product Specification:

Sterile EMR Cementless Stem

- EMR Cementless Stem – Proximal Part – Ti+HA Coated*
- EMR Cementless Stem – Proximal Part – Ti Coated*
- EMR Cementless Stem – Distal Part – Ti Coated*
- EMR Cementless Stem – Fixation Bolt*
- EMR Cementless Stem – Proximal Part*
- EMR Cementless Stem – Proximal Part for Modular Neck*
- EMR Cementless Stem – Distal Part*
- EMR Cementless Stem – Distal Part – Anatomic*
- EMR Cementless Stem – Proximal Part – Porous Coated*
- EMR Cementless Stem – Distal Part – Porous Coated*
- EMR Cementless Stem – Distal Part – Ti+HA Coated*
- EMR Cementless Stem – Proximal Part – HA Coated*
- EMR Cementless Stem – Distal Part – HA Coated*
- EMR Cementless Stem – Modular Neck - Straight*
- EMR Cementless Stem – Modular Neck - Angled*

Non Sterile Bone Plates

Non Sterile Bone Screws

Non Sterile Bone Wires

Non Sterile Fixation Systems

Non Sterile Bone Screws

Non Sterile Nails

Non Sterile Spinal Fixation Systems

Non Sterile Nails



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