

EC CERTIFICATE

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

Full Quality Assurance System

Certificate Number: 2195-MED-381424001

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

Product(s): Sterile Orthopaedic Implants

Model(s): Product specifications are stated on the following page(s).

Reference Report No: MM0184-P004-R01, MM0184-P004-R02, MM0184-P005-R01, MM0184-P005-R02, MM0184-P008-R01, MM0184-P008-R02, MM0184-P008-R03

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II (excluding section 4), 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). For class I devices with sterile conditions the quality management system evaluation is restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions. For class I devices with measuring function the quality management system evaluation is restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements.

This EC certificate is valid till 2023-10-23.

Issue Date: 2014-08-28
Revision No.: 06 Rev.
Revision Date: 2021-05-21



Rukiye BALKAN
Deputy General Manager

Certificate Number: 2195-MED-381424001

Product Specifications:

Sterile QUADROFIT Total Knee System

QUADROFIT Cemented Tibial Component
QUADROFIT Tibial Component Half Spacer
QUADROFIT Tibial Component Half Spacer Screw

QUADROFIT Standard Cemented Femoral Component
QUADROFIT Posterior Stabilized Cemented Femoral Component
QUADROFIT Standard Cementless Femoral Component-Ti+HA Coated
QUADROFIT Standard Cementless Femoral Component-Dual Coated
QUADROFIT Posterior Stabilized Cementless Femoral Component-Ti+HA Coated
QUADROFIT Posterior Stabilized Cementless Femoral Component-Dual Coated
QUADROFIT Standard Cemented Femoral Component-TiN Coated
QUADROFIT Posterior Stabilized Cemented Femoral Component-TiN Coated
QUADROFIT Standard Cementless Femoral Component-TiN Coated
QUADROFIT Posterior Stabilized Cementless Femoral Component-TiN Coated

QUADROFIT Standard Tibial Insert
QUADROFIT Posterior Stabilized Tibial Insert
QUADROFIT Standard Constrained Tibial Insert
QUADROFIT Standard Hyperflex Tibial Insert
QUADROFIT Posterior Stabilized Hyperflex Tibial Insert

QUADROFIT Mobile Bearing Standard Deep Dish Tibial Insert
QUADROFIT Mobile Bearing Posterior Stabilized Deep Dish Tibial Insert
QUADROFIT Mobile Bearing Standard Tibial Insert
QUADROFIT Mobile Bearing Posterior Stabilized Tibial Insert
QUADROFIT Mobile Bearing Standard Constrained Tibial Insert
QUADROFIT Mobile Bearing Standard Hyperflex Tibial Insert
QUADROFIT Mobile Bearing Posterior Stabilized Hyperflex Tibial

QUADROFIT Mobile Bearing Cemented Tibial Component
QUADROFIT Mobile Bearing Cementless Tibial Component-Ti+HA Coated
QUADROFIT Mobile Bearing Cemented Tibial Component-TiN Coated
QUADROFIT Mobile Bearing Cementless Tibial Component-TiN Coated
QUADROFIT Mobile Bearing Cementless Tibial Component-Dual Coated
QUADROFIT Mobile Bearing Cementless Tibial Component

QUADROFIT Tibial Stem
QUADROFIT Tibial Stem – TiN Coated
QUADROFIT Tibial Stem-Ti+HA Coated

QUADROFIT Mobile Bearing Cementless Tibial Stem-Dual Coated
QUADROFIT Mobile Bearing Tibial Stem
QUADROFIT Mobile Bearing Tibial Stem – TiN Coated
QUADROFIT Tibial Component Screw

QUADROFIT Inset Patella Component
QUADROFIT Resurfacing Patella Component



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Product Specifications:

Sterile and Non-Sterile Spinal Fixation Systems

Anterior Cervical Systems
Posterior Cervical Systems
Cervical Cages
Lumbar Cages
Posterior Spinal Systems
Dynamic Axial Systems
Servical Disc Prothesis
Lumbar Disc Prothesis
Expandable Corpectomy Cages

Non-Sterile Bone Plates and Screws

Non-Sterile Bone Nails



SZUTEST

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Product Specifications:

Sterile Cemented Cup

Sterile Modular Straight Stem

*Modular Straight Cemented Stem
Modular Straight Cementless Stem*

Sterile Optifit Cementless Cup

*Optifit Cementless Cup Ti+HA Coated
Ceramic Liner for Optifit Cementless Cup
PE Liner for Optifit Cementless Cup
Cancellous Bone Screw*

Sterile Zweymuller Modular Cementless Stem

*Zweymuller Modular Straight Cementless Stem
Zweymuller Modular Straight Cementless Stem – HA Coated
Zweymuller Modular Cementless Revision Stem*

Sterile Almond Modular Stem

*Almond Modular Cementless Stem - Ti+HA Coated
Almond Modular Cemented Stem
Almond Modular Neck
Bone Plug
Stem Centralizer*

Sterile Ball Head

Sterile Bipolar Head

Sterile EMR Cementless Stem

*EMR Cementless Stem - Proximal Part – Standard
EMR Cementless Stem - Fixation Bolt
EMR Cementless Stem - Proximal Part
EMR Cementless Stem - Distal Part
EMR Cementless Stem - Distal Part – Anatomic
EMR Cementless Stem - Distal Part - Ti+HA Coated
EMR Cementless Stem – Revision Stem Proximal Part - Ti+HA Coated
EMR Cementless Stem - Revision Stem Distal Part - Ti+HA Coated
EMR Cementless Stem - Calcar Supported
EMR Cementless Stem - Calcar Supported - Ti+HA Coated
EMR Cementless Stem – Uncemented
EMR Cementless Stem - Uncemented - Ti+HA Coated
EMR Cementless Stem Tendon Holes – Uncemented
EMR Cementless Stem With Tendon Holes - Uncemented - Ti+HA Coated*

Sterile Quadrofit Revision Knee System

*Quadrofit-Mb Revision Hinged Cemented Femoral Component
Quadrofit Revision PS Cemented Femoral Component
Quadrofit Revision PS Cementless Femoral Component
Quadrofit MB Revision Hinged Cementless Femoral Component
Quadrofit Revision Posterior Stabilized Tibial Insert
Quadrofit-MB Revision Hinged Revision Tibial Insert
Quadrofit Revision Cemented Tibial Component
Quadrofit Revision Cementless Tibial Component
Quadrofit MB Revision Hinged Cemented Tibial Component
Quadrofit-MB Revision Hinged Cementless Tibial Component
Quadrofit Revision Cemented Tibial Wedge
Quadrofit Revision Cemented Femur Posterior Wedge
Quadrofit Revision Cemented Femur Distal Wedge
Quadrofit Revision Cemented Extension Stem
Quadrofit Revision Cementless Extension Stem
Quadrofit Revision Grooved Extension Stem
Quadrofit Revision Patella Insert / PE-UHMW Crosslinked
Quadrofit Revision Patella Insert Re-Surfacing / PE-UHMW Crosslinked
Quadrofit Revision Offset AdaptOr
Quadrofit-MB Revision Hinged Revision Bumper*



SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.

Tatlısu Mahallesi, Akif İnan Sk. No:1 Ümraniye 34774 İSTANBUL / TÜRKİYE

Certificate Number: 2195-MED-381424001

Product Specifications:

Sterile Eurofit Primary Cementless Stem

Sterile Eurofit Revision Stem

Sterile EURO-TARS Tumor and Reconstruction System

EURO-TARS Femoral Stem Anatomic Cementless - Ti Spray + HA Coated / Ti
EURO-TARS Femoral Stem Anatomic Cemented / CoCrMo
EURO-TARS Femoral Stem Anatomic Cemented - TiN Coated / CoCrMo
EURO-TARS Stem for Femoral Component Cementless - Ti Spray + HA Coated / Ti
EURO-TARS Stem for Femoral Component Cemented / CoCrMo
EURO-TARS Stem for Femoral Component Cemented - TiN Coated / CoCrMo
EURO-TARS Femoral Intramedular Connection / Ti
EURO-TARS Extension Piece / Ti
EURO-TARS Adaptor / Ti
EURO-TARS Diaphyseal Implant Femoral Component / Ti
EURO-TARS Diaphyseal Implant Tibial Component / Ti
EURO-TARS Connection Bolt / Ti
EURO-TARS Distal Femoral Body / CoCrMo
EURO-TARS Distal Femoral Body - TiN Coated / CoCrMo
EURO-TARS Arthrodesis Implant Femoral Component / Ti
EURO-TARS Arthrodesis Implant Tibial Component / Ti
EURO-TARS Femoral Component Cementless Porous Coated / CoCrMo
EURO-TARS Femoral Component Cementless TiN Coated / CoCrMo
EURO-TARS Femoral Component Cemented / CoCrMo
EURO-TARS Femoral Component Cemented - TiN Coated / CoCrMo
EURO-TARS Tibial Insert / PE-UHMW
EURO-TARS Proximal Tibial Body / Ti
EURO-TARS Tibial Component Cemented / CoCrMo
EURO-TARS Tibial Component Cemented - TiN Coated / CoCrMo
EURO-TARS Distal Femur Body Lock Mechanism / CoCrMo
EURO-TARS Femoral Component Lock Mechanism / CoCrMo
EURO-TARS Distal Femur Body Lock Mechanism - TiN Coated / CoCrMo
EURO-TARS Femoral Component Lock Mechanism - TiN Coated / CoCrMo
EURO-TARS Tibial Stem Cementless - Ti Spray + HA Coated / Ti
EURO-TARS Tibial Stem Cemented / CoCrMo
EURO-TARS Stem for Tibial Component Cementless - Ti Spray + HA Coated / Ti
EURO-TARS Stem for Tibial Component Cemented / CoCrMo
EURO-TARS Stem for Tibial Component Cemented - TiN Coated / CoCrMo
EURO-TARS Proximal Femoral Body / Ti
EURO-TARS Proximal Humerus Body / Ti
EURO-TARS Humerus Head - TiN Coated / Ti
EURO-TARS Humerus Adaptor / Ti
EURO-TARS Humerus Extension Piece / Ti
EURO-TARS Humerus Connection Bolt / Ti
EURO-TARS Distal Humerus Body / Ti
EURO-TARS Humerus Lock Mechanism / Ti
EURO-TARS Ulna Anchorage Cementless - Ti Spray + HA Coated / Ti
EURO-TARS Ulna Anchorage Cemented / CoCrMo
EURO-TARS Humerus Stem Cementless - Ti Spray + HA Coated / Ti
EURO-TARS P-Stem Humerus Stem Cementless - Ti Spray + HA Coated / Ti
EURO-TARS Humerus Stem Cemented / CoCrMo
EURO-TARS Humerus Stem Cemented - TiN Coated / CoCrMo
EURO-TARS P-Stem Femoral Stem Anatomic Cementless - Ti Spray + HA Coated / Ti
EURO-TARS P-Stem Femoral Stem Anatomic Cemented / CoCrMo
EURO-TARS P-Stem Femoral Stem Anatomic Cemented - TiN Coated / CoCrMo
EURO-TARS P-Stem for Femoral Component Cementless - Ti Spray + HA Coated / Ti
EURO-TARS P-Stem for Femoral Component Cemented / CoCrMo
EURO-TARS P-Stem for Femoral Component Cemented - TiN Coated / CoCrMo
EURO-TARS P-Stem Tibial Stem Cementless - Ti Spray + HA Coated / Ti
EURO-TARS P-Stem Tibial Stem Cemented / CoCrMo
EURO-TARS P-Stem for Tibial Component Cementless - Ti Spray + HA Coated / Ti
EURO-TARS P-Stem for Tibial Component Cemented / CoCrMo
EURO-TARS P-Stem for Tibial Component Cemented - TiN Coated / CoCrMo
EURO-TARS P-Stem Humerus Stem Cemented - TiN Coated / CoCrMo
EURO-TARS P-Stem Humerus Stem Cemented / CoCrMo
EURO-TARS P-Stem Humerus Stem Cementless - Ti Spray + HA Coated / Ti

