CERTIFICATE

EC Certificate

Full Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-11-129

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

Organization:

ZİMED MEDİKAL SANAYİ VE TİCARET LİMİTED ŞİRKETİ

Aydınlar Mahallesi 03070 Cad. No:4 Şehitkamil 27580 / Gaziantep / Turkey

Products: Upper Lower Extremity Bone Plates, DHS-DCS Plates Systems, Mini Plates Systems, Cable Plates Systems, Bone Screws, Spinal Systems, Intramedullary Nail Systems, Elastic Nail Systems, External Fixator Systems, Radiolucent Fixator Systems, Hybrid Fixator Systems, Tubular Fixator Systems, Skeleton Pin And Wires, Cemented Acetabular Cup System, Cementless Acetabular Cup System, Bipolar-Modular Head, Unipolar Head, Calcar Replacement Stem, Cemented Femoral Stem, Cementless Femoral Stem, Straight Stem, Total Knee Prostheses, Revision Knee Prostheses

The products defined at the enclosure which is the part of this certificate and contains eight (8) page. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Report Number: M.3663.09
Date of first issue: 11 November 2011
Date of last issue: 03 December 2019
Revision Number: 05
Expiry Date: 27 May 2024

Design Examination according to Medical Devices Directive 93/42/EEC Annex-II Section 4 certificate is also mandatory for class III devices covered by this certificate.

Muhteşem Gökhan Yücel
Head of Notified Body

03 December 2019, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr

CERTIFICATE

Enclosure of the EC Certificate:

Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II Section 3
Certificate Number: 1984-MDD-11-129, Revision Number: 05

Concerned medical devices;

Product: Upper Lower Extremity Bone Plates
Types: Locking Distal Anterolateral Tibia Plates, Hand Wrist Arthrodesis Plates, Locking Distal Medial Tibial Point Plates, Locking Proximal Lateral Femoral Head Plates, Patella Plates, Anterior Brim Pelvis Plates, Angled Wedge Plates 135°, Locking Reconstruction Plates, Angled Wedge Plates 90°, Rib Plate, Rib Clip, Locking LC DCP Broad Plates, Locking LC DCP Narrow Plate, Locking Distal Medial Tibial Point Plates, Locking Straight Acetabulum Reconstruction Plates, Locking 1/3 Tubular Plates, Locking Distal Radius Plates Volar, Locking Distal Clavicle Plates, Locking Distal Posterior Humerus Plates, Locking Distal Humeral Y Plates, Locking Distal Medial Humeral Plates, Locking Distal Lateral Femoral Plates, Locking Proximal Lateral Femoral Plates, Locking Proximal Medial Tibial Plates, Locking Distal Lateral Tibial Plates, Locking Distal Medial Tibial Plates, Locking Calcaneal F Plates, Locking Lateral Calcaneal Plates, Locking Clavicle Hook Plates, Locking Clavicle Plates, Locking Olecranon Plates, Locking Distal Lateral Humeral Plates, Locking Fibula Plates, Locking Pilon Plates, Trochanteric Grip Plates, Locking Proximal Lateral Femoral 3.5 Plates, Locking Curved Reconstruction Plates, Minimally Invasive Locking Proximal Lateral Tibial Plates, Locking Proximal Medial Tibial T Plates, Minimally Invasive Locking Distal Lateral Femoral Plates, Locking Proximal Lateral Tibial L Plates, Locking Proximal Lateral Humeral Plates, Locking Distal Lateral Fibula Plates, Locking Distal Fibula Plates, Locking Curved Reconstruction Plates, Eight Growth Plates, Locking Reconstruction Plates, Minimally Invasive Locking Proximal Lateral Humeral Plates, Curved Reconstruction Plates, Locking Butterfly Pelvic Plates, Locking High Tibial Osteotomy Plates, Locking Adjustable High Tibia Osteotomy Plates, High Tibial Osteotomy Plates Wedge Locking Distal Radius Plates Dorsal, Locking Distal Ulna Plates, Locking Proximal Radial Head Plates, Minimally Invasive Locking Distal Lateral Tibial Plates, Locking Coronoid Plates, Locking Calcaneal Y Plates, Quadrilateral Surface Plates, Quadrilateral Surface T Plates, Locking Scapula Glenoid Plates, Locking Scapula Plates, Locking Scapula Acromion Plates, Locking Scapula Plates, Locking Scapula Lateral Plates, Locking Winged Plates, Iliopectineal Pelvic Plates, Posterior Wall Acetabular Plates, Simphis Pubis Pelvic Plates, Pelvic Hook Plates, Acetabular Reconstruction Plates, Acetabular J Reconstruction Plates, Superior Sacroiliac Plates, Cortical Screws Ø3.5, Cortical Screws Ø 4.5, Cancellous Screws Ø 4.0

Muhteşem Gökhan Yücel
Head of Notified Body

03 December 2019, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr

CERTIFICATE

Enclosure of the EC Certificate:
Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II Section 3
Certificate Number: 1984-MDD-11-129, Revision Number: 05

Concerned medical devices;

Product: Upper Lower Extremity Bone Plates
Types: Locking Screws Ø 3.5, Cortical Screws Ø 2.4, Locking Cancellous Screws 5.5, Locking Screws Ø 2.7, Cancellous Screws 5.5, Locking Cancellous Screws Ø 4.0, Locking Cancellous Screws 6.5, Locking Screws Self Drilling Ø 5.0, Cortical Screws Ø 2.7, Locking Screws Ø 2.4, Cancellous Screws Ø 6.5, Cancellous Screws Ø 4.0, Cortex Screws Ø 2.0, Ø 3.5 Locking Screws Plug, Ø 5.0 Locking Screws Plug, Locking Screws Ø 5.0, Patellar Plates Connection Screw, Locking Cannulated Screws Ø 5.5, Locking Cannulated Screws 3.5, Locking Cancellous Cannulated Screws Ø 4.0, Locking Cannulated Screws Ø 5.0, Locking Cannulated Screws Ø 7.3, Locking Cancellous Cannulated Screws Ø 6.5, Cannulated Cortical Screws Ø 4.5, Locking Cannulated Screws Ø 6.5, Cancellous Screws, Locking Screws, Cortical Screws, Cortex Screws

Product: Dhs-Dcs Plates Systems
Types: DHS/DCS Lag Screws, Locking DHS Plates 135°, Locking DCS Plates 95°, DHS / DCS Lag Compression Screws, DHS/DCS Washer Compression Screws, Compression Bolt Screws, Cancellous Screw Ø 6.5, Locking Screw Ø 5.0, Cortical Screw Ø 4.5

Product: Mini Plates Systems
Types: Straight Maxillofacial Plates, Maxillary Bone Plates, Mandible Plates, Y- Maxillofacial Plates, Y Mini-Plates, X- Maxillofacial Plates, X Bone Plates , H Bone Plates , T- Maxillofacial Plates, T Bone Plates, L- Maxillofacial Plates, Z Bone Plates , 130 ° Plates, 100 ° Plates, Orbital Floor Plates, Square Tip Maxillofacial Plates, Square Bone Plates, Self-Tapping/Self-Drilling Screw, Self-Tapping Screw Ø 1, Self-Tapping Screw Ø 1.5, Y Bone Plates, X Bone Plates, H Bone Plates, T Bone Plates, T Mini-Plates, L Mini-Plates, Z Bone Plates, Straight Mini-Plates, Straight Maxillofacial Plates, Maxillary Bone Plates, Straight Locking Bone Plates, Straight Plates, X Mini-Plates, X Maxillofacial Plates, U Mini-Plates, U Locking Bone Plates, U Plates, H Mini-Plates, T Mini-Plates, L Mini-Plates, Z Mini-Plates, 100 ° Mini-Plates, 130° Mini-Plates, Square Plates, Square Locking Bone Plates, Self-Tapping Screw Ø 2.0, Straight Mini-Plates, General Plates, Double Sided Compression, Locking Plates, Straight Plates, Locking Plates, Self-Tapping Locking Screw Ø 2.4, Titanium Mesh. (Rectangular spongy), Titanium Mesh. (Square spongy), Titanium Mesh. (Square ve Circular spongy), Titanium Mesh. (Hexagon Spongy)

Muhteşem Gökhan Yücel
Head of Notified Body

03 December 2019, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr

CERTIFICATE

Enclosure of the EC Certificate:
Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II Section 3
Certificate Number: 1984-MDD-11-129, Revision Number: 05

Concerned medical devices;

Product: Mini Plates Systems
Types: Titanium Mesh. (Y Circular spongy), Straight Locking Bone Plates, Double Sided Compression &Locking Plates, Self-Tapping Screw Ø 1.5 , Self-Tapping Screw Ø 2.0, Straight Phalange Plates, Metacarpal Straight Plates, T Phalange Plates, T Metacarpal Plates, L Phalange Plates, L Metacarpal Plates, Oblique L Phalange Plates, Oblique L Metacarpal Plates, W-Metacarpal Plates, Locking Carpal Fusion Plates, Locking LCP Straight Plates, Locking LCP Straight Reconstruction Plates, Locking LCP T Plates, Locking LCP Y Plates, Locking LCP Straight Plates, Locking LCP Straight Reconstruction Plates, Locking LCP T Plates, Locking LCP Y Plates, Locking LCP Straight Plates, Locking LCP Straight Reconstruction Plates, Locking LCP L Plates, Locking LCP Oblique L Plates, Cortex Screw 2.0, Locking Screw 2.0, Cortex Screw Ø 2.4, Locking Screw Ø 2.4, Cortex Screw Ø 2.7, Self-Tapping Screw Ø 1.5, Self-Tapping Screw Ø 2, Locking Cannulated Screw Ø 2.0, Locking Cannulated Screw Ø 2.4, Locking Cannulated Screw Ø 2.7, Cortex Screw Ø 1.5, Locking Screw Ø 1.5

Product: Cable Plates Systems
Types: Locking Attachment Plates, Attachment Grip Plates, Cable Locking Broad Plates, Locking Attachment Plates Connection Screws Ø 3.5, Locking Attachment Plates Connection Screws Ø 5.0, Cable Adapter Locking Screws Ø 3.5, Cable Adapter Locking Screws Ø 5.0, Cable Adapter Locking Screws

Product: Bone Screws
Types: Cannulated Screws Ø4.5, Cannulated Screws Ø7.3, Cannulated Screws Ø3.5, Cannulated Herbert Screws Ø3.0, Headless Cannulated Screws Ø2.5, Headless Cannulated Screws Ø3.5, Headless Cannulated Screws Ø4.0, Headless Cannulated Screws Ø5.0, Headless Cannulated Screws Ø6.5, Cannulated Dynamic Traction Screws Ø3.0, Cannulated Dynamic Traction Screws Ø4.0, Cannulated Dynamic Traction Screws Ø5.0, Cannulated Dynamic Traction Screws Ø6.0, Cannulated Dynamic Traction Screws Ø7.0, Cannulated Cortical Screws Ø4.5, Interference Screws Ø7.0, Interference Screws Ø8.0, Interference Screws Ø9.0, Transfix Screws Ø3, Malleolar Screws Ø4.5, Washers Ø3.5, Washers Ø4.5, Washers Ø6.5, Washers Ø7.3, Cannulated Screws, Cannulated Herbert Screws, Headless Cannulated Screws, Cannulated Dynamic Traction Screws, Cannulated Cortical Screws, Interference Screws, Screw Washers

Muhteşem Gökhan Yücel
Head of Notified Body

03 December 2019, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr

CERTIFICATE

Enclosure of the EC Certificate:
Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II Section 3
Certificate Number: 1984-MDD-11-129, Revision Number: 05

Concerned medical devices;
Product: Spinal Systems
Types: Polyaxial Screws Ø4.5, Polyaxial Screws Ø5.5, Polyaxial Screws Ø6.5, Polyaxial Screws Ø7.5, Polyaxial Screws Ø8.5, Monoaxial Screws Ø4.5, Monoaxial Screws Ø5.5, Monoaxial Screws Ø6.5, Monoaxial Screws Ø7.5, Monoaxial Screws Ø8.5, Spondylolisthesis Polyaxial Screws Ø4.5, Spondylolisthesis Polyaxial Screws Ø5.5, Spondylolisthesis Polyaxial Screws Ø6.5, Spondylolisthesis Polyaxial Screws Ø7.5, Spondylolisthesis Polyaxial Screws Ø8.5, Spondylolisthesis Monoaxial Screws Ø4.5, Spondylolisthesis Monoaxial Screws Ø5.5, Spondylolisthesis Monoaxial Screws Ø6.5, Spondylolisthesis Monoaxial Screws Ø7.5, Spondylolisthesis Monoaxial Screws Ø8.5, Spinal Rods Ø5.5, Transvers Connectors Crosslinks, Angled Transvers Connectors, Lamina Hooks, Pedicle Hooks, Angled Laminar Hooks, Axial Connectors, Domino Connectors, Polyaxial Screws (I Type) Ø5,5, Polyaxial Screws (I Type) Ø6,5, Cervical, Percutaneous Facet Distraction Implant, Cervical, Percutaneous Facet Distraction Implant (HA Coating), Lumbar, Percutaneous Facet Distraction Implant, Lumbar, Percutaneous Facet Distraction Implant (HA Coating), Posterior Cervical Polyaxial Screws Ø3.5, Posterior Cervical Polyaxial Screws Ø4.0, Posterior Cervical Monoaxial Screws Ø3.5, Posterior Cervical Monoaxial Screws Ø4.0, Cervical Occipital Screws, Cervical Plate-Rods, Angled Rods, Posterior Rods, Cervical Connectors, Transvers Connectors, Occipital Plates, Cervical Dominos, Posterior Cervical Plates, Occipital Cervical Plates, Posterior Dynamic Rods, Cervical Cannulated Facet Compression Screws Ø4.0, Cervical Cannulated Facet Compression Screws Ø5.0, Cannulated Facet Compression Screws Ø4.5, Cannulated Facet Compression Screws Ø5.0, Cannulated Facet Compression Screws Ø4.5 HA Coating, Cannulated Facet Compression Screws Ø5.0 HA Coating, Polyaxial Screws Ø4.5 HA Coating, Polyaxial Screws Ø5.5 HA Coating, Polyaxial Screws Ø6.5 HA Coating, Polyaxial Screws Ø7.5 HA Coating, Polyaxial Screws Ø8.5 HA Coating, Spondylolisthesis Polyaxial Screws Ø4.5 HA Coating, Spondylolisthesis Polyaxial Screws Ø5.5 HA Coating, Spondylolisthesis Polyaxial Screws Ø6.5 HA Coating, Spondylolisthesis Polyaxial Screws Ø7.5 HA Coating, Anterior Cervical Disc Prosthesis, Posterior Polyaxial Screws Ø4.5, Posterior Polyaxial Screws Ø5.5, Posterior Polyaxial Screws Ø6.5, Posterior Polyaxial Screws Ø7.5, Posterior Cervical Laminoplasty Plates, Posterior Cervical Laminoplasty Stepped Straight Plates, Posterior Cervical Laminoplasty STEPPED T Plates, Posterior Cervical Laminoplasty Plates, Self-Drilling Posterior Cervical Screws Ø2.0, Self-Drilling Posterior Cervical Screws Ø2.4, Self-Tapping Posterior Cervical Screws Ø2.4, Hybrid Posterior Cervical Rods, Posterior Cervical Hooks, Cervical Occipital Screws, Transvers Hooks, Servical Transverse Connector Rod, Sacrum Screws Ø4.5, Sacrum Screws Ø5.5, Sacrum Screws Ø6.5

Muhteşem Gökhan Yücel
Head of Notified Body

03 December 2019, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr

CERTIFICATE

Enclosure of the EC Certificate:
Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II Section 3
Certificate Number: 1984-MDD-11-129, Revision Number: 05

Concerned medical devices;

Product: Intramedullary Nail Systems
Types: Proximal Femoral Nails (PFN), PFN Proximal Lag Screws, Proximal Femoral Nail (PFN) End Caps, Nail Locking Screws, Intramedullary Femoral Nails, Intramedullary Femoral Nails, PFNA Lag End Caps, Antegrade Femoral Nail End Caps, Cannulated Intramedullary Tibia Nails, Tibial Nail End Caps, Cannulated Intramedullary Humeral Nails, Humeral Nail End Caps, Retrograde Femoral Nail End Caps, Cannulated Intramedullary Retrograde Femoral Nails, Cannulated PFN Long Nails, ZTN Tibia Nails End Caps, ZTN Tibia Nails, ZFN Multi-Purpose Femoral Nails, Distal Nail Locking Screws, Proximal Nail Locking Screws, Femoral Nail Distal Locking Screws, Femoral Nail Cannulated Proximal Locking Screws, Nail Locking Screws, Intramedullary Compression Nails (ICN) Femoral, Intramedullary Compression Nails (ICN) Tibia, Intramedullary Compression Nails (ICN) Humeral, PFNA Proximal Femoral Nails, PFNA Nails End Caps, PFNA Lag Locking Screws, PFNA Lag Screws, PFNA Lag Screws Spiral Blade, PFNA Integrated Locking Sliding Lag Screws, PFNA Integrated Anti-Rotation Compression Screws, ZFN Multi-Purpose Femoral Nail End Caps, Femoral Nail Proximal Locking Screws, PFN Lag Screws Locking Screws, Locking Sliding Lag Screws, Femoral-Tibia Arthrodesis Nails, Ankle Fusion Nails, Intramedullary Retrograde Ulnar Nails End Caps, Intramedullary Retrograde Ulnar Nails, Intramedullary Radius Nails End Caps, Intramedullary Radius Nails, Intramedullary Fibula Nails End Caps, Intramedullary Fibula Nails, Intramedullary Nail Locking Screws

Product: Elastic Nail Systems
Types: Elastic Nails, Elastic Nail End Caps, Elastic Nail Locking Screws Ø2.0, Elastic Nail Locking Screws Ø2.4, Elastic Nail Locking Screws Ø2.7, Elastic Nail Locking Screws Ø3.5, Elastic Nail Locking Screws, Locking Elastic Nails

Product: External Fixator Systems
Types: Dynamic Axial External Fixators Femoral-Tibia, Dynamic Axial External Fixators Humeral, Wrist External Fixators, Dynamic Axial External Fixators Pelvic, Limb Lengthener Fixators, Pilon Fixators, Segmental Fixators, Finger Fixators, Finger Fixator (Joint), Dynamic Fixators, Lengthener Finger Fixators, T Clamp (Femoral-Tibia), Humeral T Clamp, 135° Clamp On, 135° Clamp Off

Muhteşem Gökhan Yücel
Head of Notified Body

03 December 2019, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr

CERTIFICATE

Enclosure of the EC Certificate:
Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II Section 3
Certificate Number: 1984-MDD-11-129, Revision Number: 05

Concerned medical devices;

Product: External Fixator Systems
Types: Multi Axial Fixator Movable T Clamp, Multi Axis Fixator Multi Pin Holder Clamp, Multi Axial Fixator Compression Distraction Tube, Multi Axial Fixator Tube/Rod, Multi Axial Fixator Rod-Rod Clamp, Segmental Humeral Fixators, Wrist Fixators, Multi Axial Pin-Rod Clamps, Extremite Elbow Fixators, Cortical One Step Pins Ø2 (HA Coating), Cortical One Step Pins Ø3 (HA Coating), Cortical One Step Pins Ø4 (HA Coating), Cortical One Step Pins Ø5 (HA Coating), Cortical One Step Pins Ø6 (HA Coating), Schanz Screws Cortical Thread Ø2, Schanz Screws Cortical Thread Ø3, Schanz Screws Cortical Thread Ø4, Schanz Screws Cortical Thread Ø5, Schanz Screws Cortical Thread Ø6, Schanz Screws Spongioz Thread Ø2, Schanz Screws Spongioz Thread Ø3, Schanz Screws Spongioz Thread Ø4, Schanz Screws Spongioz Thread Ø5, Schanz Screws Spongioz Thread Ø6

Product: Radiolucent Fixator Systems
Types: Radiolucent Femoral Tibial Fixators, Radiolucent Wrist Fixators, Radiolucent Pilon Fixators, Radiolucent Finger Fixators, Radiolucent Compression Wrist Fixator, Radiolucent Wrist Fixators, Radiolucent Proximal Tibial Fixators, Radiolucent Hallux Fixator (Wire Fixator)

Product: Hybrid Fixator Systems
Types: Hybrid Fixators, Hybrid Fixator Rings, Hybrid Fixator Rod Clamps, Hybrid Fixator Wire Clamps, Hybrid Fixator Rod Connection Part, Hybrid Clamps, Hybrid Fixator Rods, Hybrid Kirschner Clamps, Hybrid Schanz Clamps, Hybrid Fixator Ring Connection Clamps, Hybrid Compression Distraction Units, Schanz Screws Cortical Thread Ø2, Schanz Screws Cortical Thread Ø3, Schanz Screws Cortical Thread Ø4, Schanz Screws Cortical Thread Ø5, Schanz Screws Cortical Thread Ø6, Schanz Screws Spongioz Thread Ø2, Schanz Screws Spongioz Thread Ø3, Schanz Screws Spongioz Thread Ø4, Schanz Screws Spongioz Thread Ø5, Schanz Screws Spongioz Thread Ø6, Kirschner Wires Trocar Point Ø0.8, Kirschner Wires Trocar Point Ø1, Kirschner Wires Trocar Point Ø1.2, Kirschner Wires Trocar Point Ø1.4, Kirschner Wires Trocar Point Ø1.5, Kirschner Wires Trocar Point Ø1.8, Kirschner Wires Trocar Point Ø2, Kirschner Wires Trocar Point Ø2.2, Kirschner Wires Trocar Point Ø2.5, Kirschner Wires Trocar Point Ø2.6, Kirschner Wires Trocar Point Ø3, Kirschner Wires Trocar Point Ø3.5, Kirschner Wires Trocar Point Ø4, Kirschner Wires Trocar Point, Kirschner Wires Bayonet Point Ø1.8, Kirschner Wires Bayonet Point Ø1.8, Kirschner Wires Bayonet Point Ø2

Muhteşem Gökhan Yücel
Head of Notified Body

03 December 2019, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr

CERTIFICATE

Enclosure of the EC Certificate:
Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II Section 3
Certificate Number: 1984-MDD-11-129, Revision Number: 05

Concerned medical devices;

Product: Hybrid Fixator Systems
Types: Thread Kirschner Wires Ø0.5, Thread Kirschner Wires Ø0.8, Thread Kirschner Wires Ø1, Thread Kirschner Wires Ø1.2, Thread Kirschner Wires Ø1.5, Thread Kirschner Wires Ø1.8, Thread Kirschner Wires Ø2, Thread Kirschner Wires Ø2.2, Thread Kirschner Wires Ø2.5, Thread Kirschner Wires Ø3, Thread Kirschner Wires Ø3.5, Thread Kirschner Wires Ø4, Thread Kirschner Wires, Hybrid Femoral-Tibia Fixators, Cortical One Step Pins Ø2 (HA Coating), Cortical One Step Pins Ø3 (HA Coating), Cortical One Step Pins Ø4 (HA Coating), Cortical One Step Pins Ø5 (HA Coating), Cortical One Step Pins Ø6 (HA Coating), Olive Kirschner Wires

Product: Tubular Fixator Systems
Types: 135° Clamp On, 135° Clamp Off, Lower Extremity External Fixator Straight Connection Part, Lower Extremity 30 Degree Connection Part, Upper Extremity External Fixator Straight Connection Part, Upper Extremity 30 Degree Connection Part, Upper Extremity External Tubular Fixator Rod, Lower Extremity External Tubular Fixator Rod, Upper Extremity External Tubular Fixator Multiplanar Pin Holder Clamp, Lower Extremity External Tubular Fixator Multiplanar Pin Holder Clamp, Upper Extremity External Tubular Angled Corner Ring, Upper Extremity External Tubular Fixator Double Planar Pin Holder Clamp, Lower Extremity External Tubular Fixator Double Planar Pin Holder Clamp, Upper Extremity External Fixator Rod-Rod Clamp, Lower Extremity External Fixator Rod-Rod Clamp, Upper Extremity External Fixator Rod-Schanz Clamp, Lower Extremity External Fixator Rod-Schanz Clamp, Upper Extremity External Tubular Fixator Trochanter Pin Holder Clamp, Lower Extremity External Tubular Fixator Angled Corner Ring, Upper Extremity External Tubular Fixator Rod, Lower Extremity External Tubular Fixator Rod, Multiaxial Fixator Dynamic T Clamp, Multiaxial Pin-Rod Clamp, Mini Tubular Fixator Tube, Mini Tubular Fixator Clamp, Mini Tubular Fixator Kit

Product: Skeleton Pin And Wires
Types: Steinmann Pins, U Staples, Cables, Cerclage Wires, Guide Wires, Kirschner Wires

Product: Cemented Acetabular Cup System **Class III**

Product: Cementless Acetabular Cup System **Class III**

Product: Bipolar- Modular Head **Class III**

Product: Unipolar Head **Class III**

Muhteşem Gökhan Yücel
Head of Notified Body

03 December 2019, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr

CERTIFICATE

Enclosure of the EC Certificate:
Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II Section 3
Certificate Number: 1984-MDD-11-129, Revision Number: 05

Concerned medical devices;

Product: Calcar Replacement Stem	**Class III**
Product: Cemented Femoral Stem	**Class III**
Product: Cementless Femoral Stem	**Class III**
Product: Straight Stem	**Class III**
Product: Total Knee Prostheses	**Class III**
Product: Revision Knee Prostheses	**Class III**

Kiwa Belgelendirme Hizmetleri A.Ş. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

Muhteşem Gökhan Yücel
Head of Notified Body

03 December 2019, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr