



# EC CERTIFICATE

## Full Quality Assurance System Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

Company Name : Normmed Medikal ve Makina San. Tic. Ltd. Şti.

Company Address : İvedik OSB 1468, Cadde No:193 Yenimahalle ANKARA / TURKEY

Related Directives and Annex : 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)

Product : 1- Plates and Screws - Class IIb - Non-Sterile  
2- Nails - Class IIb - Non-Sterile  
- Femur Nails  
- Tibia Nails  
- Humerus Nails  
3- Kirschner Wire - Class IIb - Non-Sterile

GMDN : 56642, 56643, 56645, 61573, 35241, 16101, 46638

Product Types are attached.

Certificate Number : M.2016.106.6594  
Report Number : MD.1003.YB  
Initial Assessment Date : 30.03.2016  
Registration Date : 12.04.2016  
Recertification Assessment Date : 18.02.2020  
Reissue Date : 21.12.2020/01  
Revision Date /No : -  
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UDEM hereby declares that the requirements of Annex II, excluding section 4 of the 93/42/EEC Directive have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the aforementioned directive. According to Annex II, section 4 an EC design- examination certificate is required for placing the Class III devices on the market. UDEM's responsibility for class I devices covered by the EC certificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the device is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returned upon request. The above named company and UDEM must keep copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, the mentioned

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This document containing 4 (four) pages is the Annex of the Certificate with the number M.2016.106.6594 and with the registration date of 12.04.2016 and with the re-issue date 21.12.2020 issued for "Normmed Medikal ve Makina San. Tic. Ltd. Şti." by UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. that is giving service as Notified Body with the ID No: 2292 according to 93/42/EEC Medical Devices Directive.

Plates ve Screws – Class IIb – Non Sterile
Distal Clavicle Locking Plate (3-4-5-6-7-8-9-10 Perforated)
S-Clavicle Locking Plate (4-5-6-7-8-9-10 Perforated)
Clavicle Hook Locking Plate (3-4-5-6-7 Perforated)
Anterior Clavicle Locking Plate (3-5-7 Perforated)
Modular Forefoot Locking Plate (4,6,8,10 Perforated)
Modular Backfoot Locking Plate (4,6,8,10 Perforated)
Modular Backfoot Reconstruction Locking Plate (6,8,10 Perforated)
Modular Backfoot Osteotomy Locking Plate (4,6,8,10 Perforated)
Modular Backfoot ArthrodesisLocking Plate (4,6,8,10 Perforated)
Lapidus Locking Plate (4,6,8,10,12 Perforated)
Calcaneus Displacement Plate (4,6,8,10 Perforated)
Proximal Humeral Locking Plate (3-4-5-6-7-8-9-10-11-12-13-14-16 Perforated)
Distal Humerus Extra-Articular Locking Plate (3-4-5-6-7-8-9-10-11-12-13 Perforated)
Distal Medial Humeral Locking Plate (3-4-5-6-7-8-9-10-11-12-13 Perforated)
Distal Lateral Humeral Locking Plate (3-4-5-6-7-8-9-10-11-12-13 Perforated)
Distal Posterolateral Humeral Locking Plate (3-4-5-6-7-8-9-10-11-12-13 Perforated)
Olecranon Locking Plate (3-4-5-6-7-8-9-10-11-12 Perforated)
Humeral Locking Plate (4-5-6-7-8-9-10-11-12-13-14-15-16 Perforated)
Small Fragment Locking Plate (4-5-6-7-8-9-10-11-12-13-14 Perforated)
Distal Volar Radius Locking Plate (2-3-4-5-6-7-8-9-10 Perforated)
Reconstruction Locking Plate (4-5-6-7-8-9-10-11-12-13-14-16-18-20 Perforated)
Curved Reconstruction Locking Plate (4-5-6-7-8-9-10-11-12-13-14-16-18-20 Perforated)
Distal Medial Tibial Locking Plate (4-5-6-7-8-9-10-11-12-13-14-16 Perforated)
Distal Anterolateral Tibial Locking Plate (4-5-6-7-8-9-10-11-13-15-17 Perforated)
LISS Tibial Locking Plate (4-5-6-7-8-9-10-11-12-14-15-16 Perforated)
Distal Lateral Fibular Locking Plate (4-5-6-7-8-9-10-11-12-14 Perforated)
Distal Posterolateral Fibula Locking Plate (3-4-5-6-7 Perforated)
Distal Fibular Locking Plate (4-5-6-7-8-9-10-11-13 Perforated)
Small Metaphyseal Locking Plate (4-5-6-7-8-9-10-11-12-14-16-18 Perforated)
Calcaneal Locking Plate (47mm - 57mm - 67mm - 77mm - 87mm)
Tubular Locking Plate (4-5-6-7-8-9-10-11-12-13-14 Perforated)
Proximal Radius Locking Plate (2-3-4-5-6 Perforated)
Narrow Compression Locking Plate (4-5-6-7-8-9-10-11-12-13-14-15-16-18-20 Perforated)
Broad Compression Locking Plate (4-5-6-7-8-9-10-11-12-13-14-15-16-18-20 Perforated)
Proximal Femoral Locking Plate (4-5-6-7-8-9-10-11-12-13-15 Perforated)
Distal Femoral Locking Plate (4-5-6-7-8-9-10-11-12-13-15 Perforated)
Dynamic Hip Screw (DHS) Locking Plate (4-5-6-7-8-9-10-11-12-13-14-15-16-18-20 Perforated)
Dynamic Condylar Screw (DCS) Locking Plate (4-5-6-7-8-9-10-11-12-13-14-15-16-18-20 Perforated)
DHS/DCS Lag Screw (50mm-55mm-60mm-65mm-70mm-75mm-80mm-85mm-90mm-95mm-100mm-105mm-110mm-115mm-)
Proximal Lateral Tibial Large Locking Plate (4-5-6-7-8-9-10-11-12-13-15 Perforated)
Proximal Lateral Tibial Locking Plate (4-5-6-7-8-9-10-11-12-14 Perforated)
Proximal Posteriomedial Tibial Locking Plate (3-4-5 Perforated)
Distal Lateral Tibial Locking Plate (4-5-6-7-8-9-10-11-12-13 Perforated)
Distal Postero Tibial Locking Plate (3 Perforated)
T-Locking Plate (3-4-5-6-7-8-9-10-11-12 Perforated)
Mini T Plate (4-6 Perforated))
Hole Spacing Mini T Plate (4-5-6 Perforated)
Mini Double T Plate ( 6 Perforated)
Angled Mini T Plate
L-Buttress Locking Plate (3-4-5-6-7-8-9-10-11-12 Perforated)
Hole Spacing Micro T Plate (4 Perforated) (7.5 mm-9mm-12mm)
Micro Double T Plate (6 Perforated)
Large Metaphyseal Locking Plate (3-4-5-6-7-8-9-10-11-12-14-16-18-20 Perforated)





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Proximal Lateral Tibial Extra Large Locking Plate (4-5-6-7-8-9-10-11-12-13-15 Perforated)
Ilischium Pelvic Locking Plate (4-5-6-7-8-9-10-11-12 Perforated)
Pubic Locking Plate (4-6 Perforated)
Distal Medial Metaphyseal Locking Plate (4-5-6-7-8-9-10-11-12-13-14-16 Perforated)
Reconstruction 4.5 mm Locking Plate (4-5-6-7-8-9-10-11-12-13-14-16-18-20 Perforated)
Cloverleaf Locking Plate (4-5-6-7-8-9-10-11-12 Perforated)
Coronoid Locking Plate (4-5-6-7-8-9-10 Perforated)
Olecranon Locking Plate (Left-Right) (3-4-5-6-7-8-9-10-11-12 Perforated)
Semi Tubular 4.5 mm Locking Plate (4-5-6-7-8-9-10-11-12-13-14-16 Perforated)
Posterior Proximal Tibia Locking Plate (4-5-6-7-8-9-10-11-12-13 Perforated)
Proximal Medial Tibia Locking Plate (4-5-6-7-8-9-10-11-12-13 Perforated)
Oblique Locking Plate (3-4-5-6-7-8-9-10 Perforated)
Distal Medial Femur Osteotomy Locking Plate (3-4-5-6-7-8-9-10 Perforated)
Distal Lateral Femur Osteotomy Locking Plate (3-4-5-6-7-8-9-10 Perforated)
High Tibia Osteotomy Locking Plate ( 3-4-5-6-7-8-9-10 Perforated)
Periprosthetic Support Plate
T-Buttress Locking Plate (3-4-5-6-7-8-9-10-11-12 Perforated)
T-3.5 mm Locking Plate (3-4-5-6-7-8-9-10-11-12 Perforated)
Locking Self Tapping Screw (08mm-09mm-.....-120mm)
Cortical Self Tapping Screw (08mm-09mm-.....-120mm)
Locking Cancellous Screw (08mm-09mm-.....-120mm)
Headless Cannulated Screw (08mm-09mm-.....-120mm)
Cannulated Compression Screw (08mm-09mm-.....-120mm)
Cancellous Screw (08mm-09mm-.....-120mm)
Locking Self Drilling Screw (08mm-09mm-.....-120mm)
Cannulated Compression Locking Screw (08mm-09mm-.....-120mm)
Mini Plate Straight (3-4-5-6-7-8-9-10 Perforated)
Mini Plate Straight Hole Spacing (2-4-5-6-8-10-12-14-16 Perforated)
Orbital Mini Plate (8-10-12 Perforated)
Orbital Micro Plate (6-7 Perforated)
Micro Bure Hole Plate
Mini Plate Narrow Straight (3-4-5-6-7-8-9-10 Perforated)
Mini Plate Broad Straight (3-4-5-6-7-8-9-10 Perforated)
Straight Micro Plate (4-6-8-12 Perforated)
Micro Plate Straight Hole Spacing (2-4-6-8-12-16 Perforated)
Broad Bridge Mini Locking Plate (3-4-5-6-7-8-9-10 Perforated)
Narrow Bridge Mini Locking Plate (3-4-5-6-7-8-9-10 Perforated)
Narrow X Mini Locking Plate (3-4-5-6-7-8-9-10 Perforated)
Broad X Mini Locking Plate (3-4-5-6-7-8-9-10 Perforated)
Broad L Mini Locking Plate (3-4-5-6-7-8-9-10 Perforated)
Broad L Oblique Mini Locking Plate (3-4-5-6-7-8-9-10 Perforated)
Mini L Plate (4-6 Perforated)
Hole Spacing Mini L Plate (4 Perforated)
Angled Mini L Plate (4 Perforated)
Hole Spacing Micro L Plate (4-5 Perforated)
Angled Mini L Plate (4 Perforated)
Narrow L Mini Locking Plate ( 3-4-5-6-7-8-9-10 Perforated)
Narrow L Oblique Mini Locking Plate (3-4-5-6-7-8-9-10 Perforated)
Narrow T Mini Locking Plate (3-4-5-6-7-8-9-10 Perforated)
Broad T Mini Locking Plate (3-4-5-6-7-8-9-10 Perforated)
Narrow T Necked Mini Locking Plate (3-4-5-6-7-8-9-10 Perforated)
Broad T Necked Mini Locking Plate (3-4-5-6-7-8-9-10 Perforated)
Extra Narrow T Necked Mini Locking Plate (3-4-5-6-7-8-9-10 Perforated)
Micro H Plate



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Mini Y Plate (4-5-6 Perforated)
Hole Spacing Y Plate (4-5-6 Perforated)
Mini Double Y Plate (6 Perforated)
Narrow Y Mini Locking Plate (3-4-5-6-7-8-9-10 Delik)
Narrow Necked Y Mini Locking Plate (3-4-5-6-7-8-9-10 Perforated)
Broad Necked Y Mini Locking Plate (3-4-5-6-7-8-9-10 Perforated)
Narrow Necked Narrow Y Mini Locking Plate (3-4-5-6-7-8-9-10 Perforated)
Broad Necked Narrow Y Mini Locking Plate (3-4-5-6-7-8-9-10 Perforated)
Narrow Necked Broad Y Mini Locking Plate (3-4-5-6-7-8-9-10 Perforated)
Broad Necked Broad Y Mini Locking Plate (3-4-5-6-7-8-9-10 Perforated)
Narrow Necked Broad Y Mini Locking Plate (3-4-5-6-7-8-9-10 Perforated)
Broad Necked Broad Y Mini Locking Plate (3-4-5-6-7-8-9-10 Perforated)
Hole Spacing Micro Y Plate (4 Perforated)
Micro Double Y Plate (6-7 Perforated)
Hole Spacing Micro Square Plate ((4-6-8-16-24 Perforated)
Screw Fixture (1,5mm-2,5mm-3,5mm-4,5mm-5,5mm-6,5mm)
Bushing
Pelvic J Plate (6-7-8-9-10-11-12-13-14-15-16 Perforated)
Radius Distal Straight Locking Plate (4-6 Perforated)
Pilon Plate (6-7-8-9-10 Perforated)
Curved Broad Locking Compression Plate (4-5-6-7-8-9-10-11-12-13-14-15-16-18 Perforated)
Trochanteric Grip
Pelvic Pubic Symphysis Locking Plate (6-7 Perforated)
Ischiadica Pelvic Locking/Unlocking Plate (6-7-8-9-10 Perforated)
Locked Additional Fixing Plate + 2 Screws (2-4 Perforated)
Cannulated Screw (20mm-22mm-.....-40mm)
Locking Peg Screw (8mm-10mm-.....-38mm)
Headless Cannulated Compression Screw (30mm-35mm-.....-100mm)
Herbert Cannulated Short Threaded Screw (10mm-11mm-.....-60mm)
Proximal Femoral Neck Locking Plate (5-6-7-8 Perforated)
Screw Fixture (3,5mm-4,5mm-.....-7,3mm)
Proximal Femoral Trochanter Locking Plat (5-6-7-8 Perforated)
Medial Malleolar Hook Locking Plete
Trochanter Fixing Plate
Malleolar Screw (20mm-25mm-.....-90mm)
Dhs / Dcs Compression Screw (0-5-10-15-20)
Lateral Femur End Cap
Hip Screw (65mm-70mm-.....-115mm)
Cable
Locking Cable Screw
Cable Locking Plate
(Ø2.0 mm Ø2.3 mm) Mini Screw (5mm-7mm-9mm-11mm-13mm-15mm-17mm)
(Ø1.6 mm- Ø1.9 mm) Micro Vida (4mm-5mm-6mm-7mm-9mm-11mm-13mm-15mm)
Nails- Class IIb – Non Sterile
Ftna Nail Screw (200mm-220mm-240mm -260mm-280mm-300mm-320mm-340mm-360mm-380mm-400mm-420 mm)
Ftna Roughshod Blade Screw (50mm-55mm-60mm-65mm-70mm-75mm-80mm-85mm-90mm-95mm-100mm-105mm-110mm-)
Ftna Self Tapping Screw (30mm-31mm-32mm-.....-120mm)
Ftna End Cup Screw (1mm-2mm....20mm)
Ten Flexible Nail Screw (1,0mm-1,5mm-1,8mm-2,0mm-2,5mm-3,0mm-3,5mm-4,0mm-4,5mm-5,0mm-5,5mm-6,0mm)
Ten End Cup Screw
Tibia Nail Screw (200mm-250mm-270mm-285mm-300mm-315mm-330mm-345mm-360mm-375mm)
Tibia Nail End Cup Screw
Humerus Nail Screw (180mm-195mm-210mm-225mm-240mm-255mm-270mm-285mm-300mm-315mm)
Humerus Nail End Cup Screw



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Lateral Intramedullary Femur Nail (320mm-340mm-.....-440mm)
Femur Nail End Cup Screw
Cannulated Tibial Intramedullary Nails (270mm-285mm-.....-375mm)
Distal Femur Nail (170mm-200mm-230 mm)
Distal Tibia Nail (150mm-200mm-250mm)
Distal Femur Nail End Screw
Distal Tibia Nail End Cap
Nail Lock Screw (20mm, 22mm, 24mm ..... 120 mm)
Ulna / Radius Nail (3-3.5-4 mm diameter 120-150-170-190-210-230-250 mm)
Fibula Nail (2.5-3-3.5 mm diameter 120-150-170-190-210 mm)
<b>Kışner Vida – Class IIb – Non Sterile</b>
Kirschner Self Tapping Screw (1,0mm-1,5mm-1,8mm-2,0mm-2,5mm)

