

EC Certificate

Full Quality Assurance System

Certificate No.:
247106-2017-CE-IND-NA-PS Rev. 0.0

Project No.:
PRJC-527633-2015-MSL-IND

Valid Until:
29 December 2020

This is to certify that the quality system of:

GPC Medical Limited

M-Block, DDA LSC, Vikas Puri,
New Delhi – 110018, India.

For design, production and final product inspection/testing of:

Sterile and Non-Sterile Orthopaedic Implants

Has been assessed with respect to:

The conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H2) of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and Date:
Høvik, 10 October 2017



For:
DNV GL NEMKO PRESAFE AS



Alessandra Rinna

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

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Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as 'Forskrift for Medisinsk Utstyr' by the Norwegian Ministry of Health and Care Services.

Certificate history

Revision	Description	Issue Date
0.0	Supersedes DNVGL (NB 0434) Certificate no: 192663-2015-CE-IND-NA following transfer to notified body functions to DNV GL Nemko Presafe AS (NB 2460)	2017-10-10

Products covered by this Certificate

Product Description	Product	Class
BONE SCREWS Stainless Steel & Titanium Regular & Self-Tapping With Head and Headless Cross Head and Hexagon Thread Length: (Short Thread, Partial Thread, Long Thread, Full Thread) Sterile / Non-Sterile	Cortical Screw 4.5, 3.5, 2.7, 2.4, 2.0, 1.5 mm, Cancellous Screw 6.5, 4.0, 3.5, mm, Cancellous Cannulated: 7.0, 4.5, 4.0, 2.7mm, Malleolar Screw 3.5, 4.5mm, Shaft Screw 3.5mm, 4.5mm, Emergency Screw 2.4, 3.5mm, Cancellous Traction Screw 6.5mm, ACL/ Interference Screw, Herbert Screw 2.7, 3.5, 4.5, 6.5mm, DHS Lag Screw – Adult/Paediatric, DHS Compression Screw / Blocket Screw, Asnis Screw With Washer 7.0mm, Bosworth Coraco Clavicular Screw, Croll (olecranon screw with washer, Garden Low Angle Screw 8.0mm, Trans fixation screw, LOCKING Screw 2.4, 3.5, 5.0mm, Locking Cancellous Screw 3.5, 6.5mm, Variable Angle Locking Screw 2.4mm, Variable Angle Locking Buttress Screw 1.8mm, Locking Headless Screw 1.5, 2.4, 3.0, 4.5, 6.5mm, Mini Cross slotted Screw 1.2, 1.5, 2.0, 2.5mm, Nut Hexagonal, Spiked Washer, Washer Small/Large	IIb
SPINAL SYSTEM – PLATES / CAGES / HOOKS / CROSSLINK CONNECTORS / RODS / STAPLES Titanium Sterile / Non-Sterile	Mono Axial Screw, Poly Axial Screw, Transverse Connector, Rod, Reduction Screw, Pedicle Hook, Lamina Hook Reduced Distance, Lamina Hook Angle Blade, Lamina Hook Narrow Blade, Lamina Hook Wide Blade, Transverse Connector, Staple, Inner Screw for Screws & Hooks, Outer Nut for Screws & Hooks, Cage, Harrington Rod, Harrington Hook, Cervical Hook Plate 2.7mm/3.5mm, Notched Spinal Plate, Steffee Plate, Steffee Screw, Rigid Plate Staple, Epiphyseal Staples,	IIb
PINS – WIRES – STAPLES – WASHERS - NUTS Stainless Steel & Titanium Regular / Self-Tapping / Self Drilling (Partial Thread, Long Thread, Full Thread) Sterile / Non-Sterile	Pin Steinman, Centrally Threaded Steinman Pin, Schanz Pin, Denham Pin, Knowles Pin, Moore Pin, Wires Krichner - Lanceolate Trocer/ Bayonet Point, Single/Double Ended, Orthopaedic Wire, Threaded Kirschner Wire, Cerclage Wire Loop, Drummer Wire, Orthopaedic Guide Wire, Sublaminar Wire, graduated K-Wire, Blount staples, Thorny Staples, Coventary Staples, Centerface Pin, Interface Pin, Spiked Washer,	IIb
NAILING SYSTEM Stainless Steel & Titanium Regular / Self-Tapping / Self Drilling	Interlocking Tibial Nail With And Without Distal Tip, , Unreamed Tibial Nail, Multi Angle Tibial Nail, Femoral Nail With and Without Distal Tip, Unreamed Femoral Nail, Femoral Nail with Proximal Dynamic Holes, Proximal Femoral Nail (PFN), Multi Angle Femoral Nail, Supracondylar/IMSC Nail, Humeral Nail, Unreamed Humeral Nail,	IIb

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<p>Cannulated – Solid Nails Reamed – Unreamed Nails and corresponding screws, locking bolts, end caps Sterile / Non-Sterile</p>	<p>Reconstruction Nail Left and Right, Hip Nails Smith Peterson (S.P. Nails), Cephalic Screws, Distal Bolt, Set Screw, Kuntscher Cloverleaf Nail, Ender’s Nail, Rush Nail, Elastic Nail, V-Nail, Bend Kuntscher Cloverleaf Nail Tibia, Square Nail for Radius and Ulna, Interlocking Nail, Gamma Nail Locking Bolts Diameter 2.9/3.4/3.9/4.5/4.9/5.9mm, IMSC Locking Bolt, Locking Bolt Cannulated Self-Tapping 6.5/7.5mm, End Caps for IMSC/Recon/PFN/Gamma/Humeral/Tibial Nails,</p>	
<p>BONE PLATES Stainless Steel & Titanium Locking & Non-Locking Round Holes & Dynamic Compression Holes, With /Without LC DCP Holes With / Without below features: - Straight Plates - Angle Plates – Left & Right - LC Under Cuts Fixed / Variable Angle Holes/Oblique</p>	<p>Condylar Plate 95° Angled Blade plates for intertrochanteric femoral osteotomies in adults 90°/100°/120°/130° Condylar Plate 95° /130° Condylar Buttress Plate, L buttress Plate, T Buttress Plate, D.H.S. Barrel Plates 125° / 130° / 135°/ 140°/ 145°/150° Variable Angle, Double Angle, Paediatric, LC-DHS Barrel Plate, D.C.S. Barrel Plate, Jewet Nail Plate 135°,130°, DCP, Mini DCP2.0mm, Mini DCP2.7mm, Small DCP3.5mm, Narrow DCP, Broad DCP, Small T Plate for 3.5mm Straight, Oblique and 4head hole, T-Plate for 4.5mm, Mini T Plate 1.5mm & 2.0mm, LC-DCP in small, narrow and broad, Reconstruction plates for 2.7mm, 3.5mm and 4.5mm, Y reconstruction plate, mandibular plate, tubular plates in 1/3rd-1/4th- semitubular & quarter tubular, Sherman plate, spoon plate, cloverleaf plate, Cobra head Plate, intertrochanteric Plate with bolt and washer, Maclaughlin Plate with Bolt and Washer, Venable Plate, Wainwright Osteotomy Plate, Kessel Osteotomy Plate, Intertrochanteric Bone Plate with bolt and washer, Distal Tibia Bone Plate Left and Right, Distal Humerus Bone Plate Left and Right, Humeral Epicondylar Plate Right and Left, Medial Proximal Tibial Bone Plate Right and Left, Proximal Humerus Bone Plate Right and Left, Proximal Femur Plate Right and Left, Lateral Tibial Head Buttress Plate Right and Left with and without LC Undercuts and LC DCP Holes, Hook Plate for 4.5mm screw, Distal Femur Plate Right and Left, Calcaneal Plate 3.5mm, Olecranon Plate, Burm Born Plate, Broad DCP Plate with ACP Holes, Broad Lengthening Plate with ACP Holes, Narrow DCP plate with ACP Holes, Broad Plate, Dorsolumbar Plate, Lecestre Plate Left & Right,</p>	<p>IIb</p>
<p>BONE PLATES Stainless Steel & Titanium Locking & Non-Locking Round Holes & Dynamic Compression Holes, With /Without LC DCP Holes With / Without below features: - Straight Plates - Angle Plates – Left & Right - LC Under Cuts Fixed / Variable Angle Holes/Oblique</p>	<p>Locking Plates: Small / Narrow / Broad Plate, T-Plate 3.5/4.5/4.5mm Buttress, L-Plate 4.5mm, Lateral Tibia Plate, Condylar Buttress Plate Left and Right, Proximal Humerus Plate, Femoral Head Plate Left and Right, Recon Plate 3.5/4.5mm, Cloverleaf Plate, Metaphyseal Plate, DHS Plate, Proximal Tibia Plate Left and Right, Distal Tibia Plate, Distal Femur Plate, T Plate 3.5 Oblique Angle, One Third Tubular Plate with Collar, recon plate 3.5 curved, Condylar Plate 2.0mm, Adaptation Plate 2.0mm, T- Plate 2.0mm, Variable Angle Volar Extra Articular Distal Radius Plate 2.4mm, Variable Angle Two Colum Volar Distal Radius Plate 2.4mm, Variable Angle Fusion Plate 2.4/2.7mm, Variable Angle Opening Wedge Osteotomy Plate, Variable Angle Navicular Plate, Variable Angle Cuboid Plate, Variable Angle Cloverleaf Fusion Plate 2.4/2.7mm, Variable Angle T- Fusion Plate 2.4/2.7mm, Variable Angle L- Fusion Plate 2.4/2.7mm, Variable Angle X-Plate 2.4/2.7mm, Variable Angle Straight Fusion Plate 2.4/2.7mm, Low Bend Medial Distal Tibia Plate, Medial Distal Tibia Plate without Tab, Periarticular Proximal Humerous Plate 3.5mm, Periarticular Plate, Adaptation Plate for 1.5 / 2.0mm screw, H Plate 1.5mm/2.0mm, L & T shaped Plates for 2.0mm screw for finger joint-head shaft with 3 holes, head with 2 pin, Straight Plate for 1.5/2.0mm screw, orbital Curved plate for 1.5/2.0mm screw, Zygomatic DCP plate 2.0mm, L Plate 2.0mm Right and Left, Y Plate 1.5mm, X-Plate 2.0mm, Double Y Plate 2.0mm, Nose Plate-X Shaped, Nose Plate, Z-Plate Left and Right, Straight Plate with and Without Bridge, Orbital Plate, Angle Plate Right and Left, Mesh Plate.</p>	<p>IIb</p>

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<p>EXTERNAL FIXATOR Stainless Steel – Carbon Fibre – Aluminium – Titanium Sterile / Non-Sterile (CLASS I Ib)</p>	<p>Tubular Fixator System (AO), Fixators for Metacarpals, Ilizarov Fixator, Distal Radius Fixator, AO Titanium Fixator System, Dynamic External Fixator, Humerus Fixator, JESS Fixator, Mini Rail Fixator, Mini Rail Lengthening Fixator, Adult Lengthening Rail Fixator, Paediatric Lengthening Rail Fixator, Tibial Plateau Fixator, Ankle Fixator, Dynamic Axial Fixator, Fixation for HTO (High Tibial Osteotomy), Hybrid Fixation System and Ring Fixator, Adult Limb Reconstruction System, Paediatric Limb Reconstruction System, Pelvic Fixator, Elbow Fixator, Dynamic Wrist Fixator, Mini Fixator, Hoffmann 1 Fixator, Hoffmann 2 Fixator,</p>	<p>I Ib</p>
<p>HIP PROSTHESIS Stainless Steel Regular Finish & Satin Finish Sterile / Non-Sterile (CLASS I Ib)</p>	<p>Austin Moore Prosthesis (Head Dia 35mm to 59mm) – Standard Stem, Narrow Stem, Broad Stem, Extra Long Stem, Thompson Prosthesis (Head Dia 35mm to 59mm) – Standard Stem, Narrow Stem, Broad Stem.</p>	<p>I Ib</p>

The complete list of devices is filed with the Notified Body.

Sites covered by this certificate

Site Name	Address
GPC Medical Ltd	M-Block, DDA LSC, Vikas Puri, New Delhi – 110018, India.

EU Representative

JOMISCH, Laan van keulen 58, 1827 KW Alkmaar, The Netherlands, Tel.: +31 6 49 9900 05,
email: contact@jomisch.nl

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Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate