

EC CERTIFICATE

Full Quality Assurance System

Certificate No.: 250028-2017-CE-IND-NA-PS Rev. 1.0
Project No.: PRJC-523541-2015-MSL-IND

Valid Until:
25 October 2021

This is to certify that the quality system of:

Greens Surgicals Pvt. Ltd.

Plot No. 508 – 512, Savli Industrial Estate, GIDC, Manjusar, Vadodara – 391 775,
Gujarat, India

For design, production and final product inspection/testing of:
NON-STERILE ORTHOPAEDIC IMPLANTS

Has been assessed with respect to:

**THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN
ANNEX II EXCLUDING SECTION 4 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, 22 November 2019

For:
DNV GL PRESAFE AS
Notified Body No.: 2460



Palani Damodharan

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html



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Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om 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: 203370-2016-CE-IND 0.0 following transfer to notified body functions to DNV GL Nemko Presafe AS (NB 2460)	2017-11-17
1.0	Editorial Changes	2019-11-22

Products covered by this Certificate:

Product Description	Product Name	Class
BONE SCREWS in Stainless Steel, Titanium & PEEK With or Without Cannulation, Regular, Self-Tapping & Self Drilling and Partial & Full Thread Length	Cortical Screws – Thread Diameters: 1.0mm/1.3mm/1.5mm/2.0mm/2.4mm/2.5mm/2.7mm/3.5mm/4.0mm/4.5mm/5.0mm/5.5mm/6.0mm Cancellous Screws - Thread Diameter: 2.0mm/ 3.5mm / 4.0mm/5.0mm/6.2mm/6.4mm/6.5mm/7.0mm/7.3mm/8.0mm/12.5mm Locking Screws – 1.5mm/2.0mm/2.4mm/2.5mm/2.7mm/3.0mm/3.5mm/4.0mm/5.0mm/6.0mm/6.5mm/8.0mm Variable Angle Screws – 2.0mm, 2.4mm, 2.7mm, 3.5mm, 4.0mm,5.0mm Malleolar – Thread Diameter: 4.5mm Herbert Screws – Thread Diameters: 3.0mm to 6.0mm Shaft Screws – Thread Diameter: 4.5mm Schanz Screws – Thread Diameter: 1.0mm/1.5mm/1.8mm/2.0mm/2.5mm/3.0mm/3.5mm/4.0mm/4.5mm/5.0mm/5.5mm/6.0mm/6.5mm DHS-DCS Screw, Compression Screw, DHS Blade Screw, Paediatric Screws, ACL-PCL Screw (Interference Screw), Suture Anchor Screw,	Iib
CRANIO-MAXILLOFACIAL SCREWS in Stainless Steel & Titanium Regular / Self-Tapping / Self Drilling and Partial & Full Thread Length	Cortical Screws – Thread Diameters: 1.0mm/1.3mm/1.5mm/2.0mm/2.4mm/2.5mm/2.7mm/3.5mm/4.0mm Cancellous Screws - Thread Diameter: 2.0mm/ 3.5mm / 4.0mm Locking Screws – Thread Diameter: 1.5mm/2.0mm/2.4mm/2.5mm/2.7mm/3.0mm/3.5mm/4.0mm	Iib
SPINAL SYSTEM SCREWS in Stainless Steel & Titanium Regular / Self-Tapping and Partial, Full & Differential Thread Length	Cortical Screw, Cancellous Screw, Cortico-Cancellous Screw, Mono-Axial Screws, Poly-Axial Screws, Reduction Screws (Listhesis Screw), Sacral Screw, Steffe Screw, Cervical Plate Screw(Standard & Locking), Odontoid Screw, Occipital Screw, Inner Screw (End Cap) Spine Washers Angle Bolts Compression and Anti-Rotation Nut	Iib

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<p>SPINAL SYSTEM - PLATES / CAGES / HOOKS / CROSSLINK CONNECTORS / RODS / STAPLES in Titanium & PEEK</p>	<p>Anterior Cervical Spine Plate, Lumbar Vertebra Titanium Plate, Thoracic Vertebra Titanium Plate, Posterior Cervical Spine Titanium Plate, Steffee plate. Rods, Harrington Rod, Angled Rod. Cross-Link Connectors, Lateral Connector. Front Staples. Hooks. Angled Clamp. Cervical Vertebra Fusion Cage, Cervical vertebrae plate with cage, Lumbar Vertebra Shutter Shape Fusion Cage, Lumbar Vertebra Z Shape Fusion Cage, Lumbar Vertebra Curved Shape Fusion Cage, Angled Titanium Mesh Cage, Round Titanium Mesh Cage. U-Spine Inter-Spinous Spacers, Kidney Shape Cage, Pliff cage, Expandable Cage.</p>	<p>Iib</p>
<p>PINS - WIRES - STAPLES - WASHERS - NUTS in Stainless Steel & Titanium Regular / Self- Tapping / Self Drilling and Partial & Full Thread Length</p>	<p>Front Threaded Pins, Tapered Pins, Cancellous Front Threaded Pins, Cortical Front Threaded Pins, Centrally Threaded Steinmann Pins, Steinmann Pins, Knowels Pins, Austin Moore Pins with Nuts, Kirschner Wires, Cerclage Wire, Threaded Guide Wire, Drummer Wire, Small Washers, Large Washers, Spike Washers, Ligaments Washer (Round & Square), Endobutton Washer U-Staples, Coventry Staples, Straight Staples, Ligaments Staples, Stool Staples, Staple with Offset, Blount Staples, Three Legged Staples, Epiphyseal Staples</p>	<p>Iib</p>
<p>NAILING SYSTEM in Stainless Steel & Titanium Regular Cannulated - Solid Nails Reamed - Unreamed Nails</p>	<p>Ender Nails, Elastic Nails, Telescopic Nails, Intramedullary Rush Nails, Kuntscher Femoral Nail, Kuntscher Tibial Nails FEMORAL NAILS -Antigrade and retrograde femur nail, Multi Fix Femoral Nails, Short and long proximal femur nails, Reconstruction Nails, , Universal Femoral Nail, Gamma Nails, PFNA2 and 3 nails, Single or multiplane interlocking femur nail, Unidirectional or multidirectional holes, Supracondylar nails TIBIAL NAILS - Single or Multiplane interlocking tibia nails Universal Tibia Nails, Multi Angle Tibia Nails, Short and Long Tibia Nails Arthrodesis Nails Humerus Nails- Short and Long Humerus Nail,Cannulated and solid, Uniplaner and Multiplaner, Unidirectional or multidirectional holes. Radius and Ulna Nails- Short and long nails square, round, interlocks, holes and uni and multi directional.</p>	<p>Iib</p>
<p>STANDARD BONE PLATES in Stainless Steel & Titanium With / Without below features & varieties: - Straight Plates - Anatomical Plates - Left & Right - Angle Plates - Left & Right - Round Hole Plates - Dynamic Compression Plates - Limited Contact Dynamic</p>	<p>SMALL AND LARGE FRAGMENT PLATES LC-LCP Locking Proximal Humerus Plates (LPHP) Ø 3.5mm, LCP Extra Articular Distal Humerus Plate -Left and Right, Dr.Vinay's Distal Condylar Humeral Locking Plate-Left and Right , Locking Upper Tibial Plate For Ø 4.5 mm- Left and Right, LC-LCP Metaphysial Plate For Ø 4.5 mm, LC-LCP Small For Ø 3.5 Mm, LC-LCP Narrow Plate For Ø 4.5 / 5.0 mm, LC-LCP Broad Plate For Ø 4.5 / 5.0 Mm, LC-LCP Combi Hole Recon Plate For Ø 3.5mm, LC-LCP1/3rd Tubular Plates For 3.5 Mm, LC-LCP Small T.Plate For Ø 3.5mm, LC-LCP T.Plate Oblique Angle For Ø 3.5 Mm- Left and Right, LC-LCP T.Plate For Ø 4.5mm, LC-LCP T.Buttress Plate For Ø 4.5 Mm, LC-LCP L.Buttress Plate For Ø 4.5 Mm- Left and Right, LC-LCP Cloverleaf Plate For Ø 3.5 Mm, LCP Calcaneal Plate, L- 60mm - Left and Right, LCP Calcaneal Plate, L- 70mm - Left and Right, DCS Barrel Plate 95° With Combi Holes, LC-LCP Distal Femoral Plate For Ø 4.5mm, LC-LCP Distal Femoral Plate For Ø 4.5mm, LC-LCP Clavicle Hook Plate - Left and Right, LC-LCP Medial Distal Tibia Plate Ø 3.5mm- Left and Right, LCP Trochanteric- Left and Right, LC-LCP Anterolateral Distal Tibia Plates Ø 3.5mm- Left and Right, LCP Two - Column Volar Distal Radius Plate 2.4mm, Variable Angle- Left and Right, 3.5 Mm LCP Dorsolateral Lower Humerus Plate With Lateral Extension- Left and Right, LCP T - Distal Radius Plate - Extra Long Head, LCP Olecranon Plate 3.5mm- Left and Right, LCP Superior Anterior Clavicle Plate 3.5mm- Left and Right, LCP Encirclage Wire Mount 5.0 Mm, LCP Calcaneus Plate- Left and Right, LC-LCP Anterolateral Distal Tibia Plates Ø 3.5 Mm, LCP Distal Fibula Plate 2.7 Mm / 3.5 mm,</p>	<p>Iib</p>

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<p>Compression Plates (LC-DCP) - Locking Compression Plate / Limited Contact Locking Compression Plate (LCP & LC-LCP) - Variable Angle Plates</p>	<p>3.5 Mm LCP Medial Distal Tibia Plate- Left and Right, LCP Medial Proximal Tibial Plate 3.5mm- Left and Right, Locking Femoral Condylar (Milc) Plate- Left and Right, High Tibial Osteotomies Locking Plate, LC-LCP Combi Hole Recon Plate For Ø 4.5mm, 3.5 Mm LCP Medial Distal Tibia Plate- Left and Right, LCP Anterior Posterior Variable Angle Clavicle Plate 3.5 Mm, LCP Distal Radius L-Plate-Dorsal Plate 90 Ø- Left and Right, LCP Distal Radius Plate – Volar-Left and Right, LCP Distal Radius Buttress Volar Plate Ø 2.4mm- Left and Right, LCP Distal Radius Straight Plate - Dorsal Plates, LCP Distal Radius T - Plate - Dorsal Plates, LCP Long Philos Plate, LC-LCP Medial Distal Humeral Plates- Left and Right, LCP Metaphysial Plate 3.5 Mm, LCP Periarticular Proximal Humerus Plate- Left and Right, LCP Proximal Tibia Plate- Left and Right, LCP Short Philos Plate, LCP Superior Anterior Clavicle Plate With Lateral Extension 3.5mm- Left and Right, LCP Variable Angle Distal Femur Plate- Left and Right, LCP Variable Angle Proximal Tibia Plate- Left and Right, LCP Volar Distal Radius Plate, Extra Articular- Left and Right, Dr. Vinay\'S Pilon Fracture Plate With Lateral Extension- Left and Right, Dr. Vinay's Pilon Fracture Plate Without Lateral Extension- Left and Right, Dhs L/B Plate With Combi Hole 135 Ø, Pelvic Recon Plate Low Profile Ø 3.5mm, Pelvic Recon Plate Low Profile (S.S.) A.O Type – Straight, Pelvic Recon Plate 88° Ø 3.5mm, Pelvic J Plate Ø 3.5mm, St. Recon Plate For 4.5 Mm Screws, Quadrilateral Surface Plate 3.5 Low Profile, Pelvic Recon Plate 88° Ø 3.5mm, Spring Plate 3.5, Pelvic Recon Plate 108° Ø 3.5mm, LCP Adaption Plate 2.0 Mm, LCP Adaption Plate 2.4 Mm, LCP Condylar Plate 2.0, LCP Condylar Plate 2.4, LCP Recon Plate 2.0mm, LCP Recon Plate 2.4mm, LCP T-Plate 2.0, LCP T-Plate 2.4, Maxillofacial Plates. Posterior medial proximal tibia. <u>DCP PLATES</u> <u>Lower Limb Plates and Upper Limb Plates:</u> DHS Barrel Plate Long Barrel Plate, Short Barrel Plate, Round Hole, DCP Hole, LC Hole, LC-LCP Hole 120°,125°,130°,135°,140°, 145°, 150°. Paediatric Barrel Plate - Long Barrel Plate, Short Barrel Plate, Round Hole, DCP Hole, LC Hole, LC-LCP Hole 120°,125°,130°,135°,140°, 145°, 150°. DCS Barrel Plate 95° - Round Hole, DCP Hole, Tubular Plate – Round Hole, DCP Hole, Quarter Tubular Plate, One Third Tubular Plate, Semi Tubular Plate, Reconstruction Plate - Mini Plate, Small Plate and Large Plate - Pelvic Plates – Straight, Curved Plate, J Plate, Y-Plate, Spring Plate, Quadrilateral Plate, Quadrangular Plate, L-Plate. T-Plate, Angular Plate. T-Plate, T Oblique Plate, L-Plate - Mini, Small, Large, Anatomical Plates, Buttress Plates, - Small T- Plate- Right Angle For 3.5mm Screw, Small T- Plate- Right Angle For 3.5mm Screw, Small T- Plate- Right Angle For 3.5mm Screw, Small T- Plate- Right Angle For 3.5mm Screw), Small T- Plate- Oblique Angle, Small T- Plate- Oblique Angle, T- Buttress, L- Buttress Plates– Left, L- Buttress– Right, Straight Recon Plate with Gap, Straight Recon Plate without Gap, and Dcp for 2.7 Mm Screws, Dcp Small Hook Plate For 3.5 Mm Screws, Cobra Plate L-170 to L-186, Calcaneal Plate, L- 60mm/ 70mm Lateral Tibial Plate, Casper Plate – Small / Medium / Large, Hip Plates for Intertrochanteric Plates 90° 120°,Condylar Blade Plate 95°, 120°, 130°, Osteotomy Barrel Plates- 110°, 120°, 130°, Cloverleaf Plates, Dynamic Compression Plates (LC-Dcp Small) For 3.5 Mm Screws, Dynamic Compression Plates (LC-Dcp Narrow) For 4.5 Mm Screws, Dynamic Compression Plates (LC-Dcp Broad) For 4.5 Mm Screws, Small Dcp for 3.5 Mm, Narrow Dcp For 4.5 Mm Screws, Broad Dcp For 4.5 Mm Screws <u>Mini Fragment / Hand & Foot System 1.3/1.5/2.0/2.4/2.5/2.7mm</u></p>
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	Dynamic Compression Plate, T Plate, T Adaptation Plate, L Plate, Straight Plate, Extended H Plate, Y Plate, Condylar Plate, Tubular Plate, Reconstruction Plate (Straight & Curved), Volar Plates, Sherman Plates, Adaptation Plate, X Plate, Spring Plate,	
CRANIO-MAXILLOFACIAL PLATES in Titanium With/Without below features: - Straight Plates - Angle Plates – Left & Right - Locking (Wise-Lock) - Non-Locking	<u>1.0mm/1.3mm/1.5mm/1.8mm/2.0mm/2.4mm/2.5mm/2.7mm System</u> 90°/120° Angled L-Plate with Bar, 90°/120° L - Plate with Bridge, 90°/120° L - Plate without Bridge, 150° Angular Plate, Continuous Hole Plate, Double Y Plate, H-Plate, Nose Plate, X Shape Nose Plate, Orbital Plate Curved, Orbital Plate with Bridge, Straight Plate with Bridge, T - Plate with Bar, T - Plate without Bridge, Y- Plate (Small & Large), Z Plate, Curved Plate, Double Y Plate, Mandible Plate, Mandible Plate with Continuous Holes, Splitfix Plate, Reconstruction Plates for Mandible Straight/Angled/ Double Angled, Long I Plate, Rectangular Frame Plate, Rectangular Grill Plate, Burr Hole Plate, Le Fort I Plate, Triangular Plate, U-Shape Reconstruction Plate for Full Mandible, Orbital Floor Plate, Nasal Bone Plate, Pseudo-Possessed Plate, One Way Pressure Plate, Maxilla Plate, Mesh Plate, Strut Plate, Clavicle Collar Plate, Spring Plate, Wainright Plates, Universal Fracture Plate (Round Holes) Angled	Iib
EXTERNAL FIXATOR in Stainless Steel – Aluminium – Titanium	Universal External Fixator System for Upper & Lower Limb and Pelvic, Ilizarov Fixator System / Ring Fixator System for Adult & Paediatric, Hybrid Fixator System, Rail Fixator System Adult & Paediatric, Mini, Small & Large Dynamic Fixator System, Extra Dural Spine Fixator System	Iib

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Greens Surgicals Pvt. Ltd.	Plot No. 508 – 512, Savli Industrial Estate, GIDC Manjusar, Vadodara – 391 775, Gujarat, India

EU Representative

Obelis s.a. Bd, General Wahis 53, 1030 Brussels, Belgium,
Tel.: +32 2 732 5954, Fax: +32 2 732 6003, email: mail@obelis.net[Country]

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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