

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:
10000363901-PA-NA-IND Rev 2

Project No.:
PRJC-500995-2014-MSL-IND

Valid Until:
27 May 2024

This is to certify that the quality system of:

Auxein Medical Private Limited

Plot No. 168-169-170, Phase-IV, Kundli Industrial Area, HSIIDC, Sector-57, Sonapat, Haryana – 131028, India

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

Orthopedic 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, 09 October 2020

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



Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.
NOTIFIED BODY: DNV GL PRESAFE AS, Veritasveien 3, N-1363 Høvik, Norway - Registered Enterprise No: NO 997 067 401 MVA .

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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	Original Certificate	07 May 2020
1.0	Editorial change in Database	11 May 2020
2.0	Addition of products	09 October 2010

Products covered by this Certificate:

Product Description	Product Name	Class
Anterior Cervical System (Sterile/Non-sterile)	<ol style="list-style-type: none"> 1. Apex Anterior Cervical Plate, Length - 22.5mm to 70mm, Material - TI 2. Apex 3.5mm Self-Tapping, Cancellous Screw, Length - 12mm to 16mm, Material - TI 3. Apex 4.0mm Self-Tapping, Cancellous Screw, Length - 12mm to 16mm, Material -TI 4. Apex 3.5mm Self-Drilling, Cancellous Screw, Length - 12mm to 16mm, Material -TI 5. Apex 4.0mm Self-Drilling, Cancellous Screw, Length - 12mm to 16mm, Material -TI 	II b
Spinal System (Sterile/Non-sterile)	<ol style="list-style-type: none"> 1. Monoaxial Screw, Length - 35mm to 55mm, Material - TI 2. Polyaxial Screw, Length - 35mm to 55mm, Material - TI 3. Reduction Polyaxial Screw, Length - 35mm to 55mm, Material - TI 4. Rod, Length - 35mm to 55mm, Material - TI 5. Inner Blocking Screw, Material - TI 6. Crosslink Connector I, Length - 39.37-44.45mm, 44.45-54.61mm, 54.61-74.93mm, Material - TI 7. Crosslink Connector II, Length - 75mm, Material - TI 	II b
Intramedullary Humerus Nailing System (Sterile/Non-sterile)	<ol style="list-style-type: none"> 1. Compression Intramedullary Humerus Nail, Length - 200mm to 320 mm, Material - TI & SS 2. Reconstruction Intramedullary Humerus Nail, Length - 200mm to 320mm, Material - TI & SS 3. Reconstruction Nail, Length - 160mm to 320mm, Material - TI & SS 4. End Cap for Compression Intramedullary Humerus Nail, Material - TI & SS 5. Compression Screw, Material - TI & SS 6. End Cap for Reconstruction Nail, Material - TI & SS 	II b

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	<p>7. 4.5mm Locking Bolt, Length – 20mm to 55mm, Material – TI & SS 8. 3.5mm Locking Bolt, Length – 20mm to 70 mm, Material – TI & SS 9. Proximal Screw Ø4.5mm for Compression Intramedullary Humerus Nail, Length – 25mm to 70mm, Material – TI & SS</p>	
<p>Intramedullary Femoral Nailing System (Sterile/Non-sterile)</p>	<p>1. Expert Femoral Nail, Length – 320mm to 440mm, Material – TI & SS 2. Gamma Nail (130degree Gamma Nail with Anti-Rotation) Short, Length – 180mm to 240mm, Material – TI & SS 3. Gamma Nail (130degree Gamma Nail with Anti-Rotation) Long, Length - 320 to 440mm, Material – TI. 4. 130° Gamma Nail, Type-II, Short, Length – 180mm, Material – TI 5. 130° Gamma Nail, Type-II, Long, Length – 320mm to 440mm, Material – TI 6. AJAX Advance Nail, Short, Length – 170mm to 240mm, Material – TI 7. AJAX Advance Nail, Long, Length – 260mm to 420mm, Material – TI 8. Retrograde Femoral Nail with End Cap, Length – 180mm to 360 mm, Material – TI 9. Intramedullary Cannulated Femur Nail, Length- 320mm to 440 mm, Material – TI & SS 10. End Cap, Expert Femoral Nail, 0mm to 20 mm, Material – TI 11. 6.4mm Cannulated Anti-Rotational Screw, Length – 60mm to 130mm, Material - TI 12. 4.8mm Locking Screws for Expert Femur Nail, Length – 26mm to 64mm, Material – TI 13. Cephalic Screw for Gamma Nail with Anti-Rotation Screw and Gamma Nail Type – II, Length -70mm to 120mm, Material - TI 14. End Cap, Gamma Nail with Anti-Rotational Screw, Length – 0mm to 15mm, Material - TI 15. End Cap, Gamma Nail, Type – II, Length – 0mm to 15 mm, Material - TI 16. 4.8mm Locking Screws, Length – 26mm to 90mm, Material - TI 17 Inner Screw (Inner Screw, Gamma Nail with Anti-Rotation Screw), Length - 19.6 mm, Material - TI. 18. Inner Screw, Gamma Nail, Type -II, Length - 19.6mm, Material - TI 19. End Cap for Cephalic Screw (Gamma Nail), Length - 18.0mm, Material - TI 20. 4.9mm Locking Bolt, Self-Tapping (Proximal Femoral Nails), Length – 26mm to 100mm, Material - TI 21. Ajax Blade, Length – 75mm to 120mm, Material - TI 22. End Cap of Ajax blade, Length – 0mm to 15 mm, Material - TI 23. End Cap of Ajax Cephalic Screw, Length - 4.90mm, Material - TI 24. Inner Screw for Ajax Cephalic Screw, Length - 24mm, Material - TI</p>	<p>II b</p>

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	<p>25. Ajax Nail End Cap for Cephalic Screw, Thread Length - 9.6mm, Material - TI</p> <p>26. End Cap for Universal Intra Medullary Cannulated Femoral Nail, Length - 11.25mm, Material - TI & SS</p> <p>27. Compression Screw for Universal Intramedullary Cannulated Femoral Nail, Material - TI & SS</p> <p>28. 4.5mm Locking Bolt for Universal Intramedullary Cannulated Femoral Nail, Length - 20mm to 90mm, Material - TI & SS</p> <p>29. 6.5mm Cannulated Reconstruction Screw, Length - 60mm to 120mm, Material - TI & SS</p> <p>30. 6.5mm Locking Bolt, Full Thread, Length - 40mm to 110mm, Material - TI & SS</p> <p>31. Blocking Set 6.5mm, Length - 50mm to 90mm, Material - TI & SS</p> <p>32. End Cap for Retrograde Femoral Nail, Length - 13mm, Material - TI</p> <p>33. 5.0mm Locking Bolt for Retrograde Femoral Nail, Length - 32mm to 80mm, Material - TI</p>	
Intramedullary Elastic Nails (Sterile/Non-sterile)	<p>1. Elastic Nails, Length - 440 mm, Material - TI.</p> <p>2. End Cap for Titanium Elastic Nail, Length - 14 mm, Material - TI.</p> <p>3. End Cap for Titanium Elastic Nail, Length - 25mm, Material - TI.</p>	II b
Intramedullary Tibia Nailing System (Sterile/Non-sterile)	<p>1. Interlocking Cannulated Tibia Nail, Length - 270mm to 390mm, Material - TI & SS</p> <p>2. Expert Tibia Nail, Length - 255mm to 375mm, Material - TI & SS</p> <p>3. End Cap for Expert Tibia Nail, Length - 0mm to 15mm, Material - TI & SS</p> <p>4. End Cap for Interlocking Tibia Nail, Length - 15mm, Material - TI & SS</p> <p>5. Compression Screw for Interlocking Cannulated Tibia Nail, Length - 44mm, Material - TI & SS</p> <p>6. 4.5mm Locking Bolt for Interlocking Cannulated Tibia Nail, Length - 20mm to 90 mm, Material - TI & SS</p> <p>7. 4.4mm Locking Bolt for Expert Tibia Nail, Length - 24mm to 88mm, Material - TI & SS</p> <p>8. 4.8mm Locking Bolt for Expert Tibia Nail, Length - 25mm to 90mm, Material - TI & SS</p>	II b
Radius system (Sterile/Non-sterile)	<p>1. Dorsal - T Plate (2.4mm Wise-Lock "T" Distal Radius Dorsal Plate, 3 Head Holes), Material - TI</p> <p>2. Straight Plate (2.4mm Wise-Lock Distal Radius Dorsal Plate, Straight), Material - TI</p> <p>3. L Plate - 2 Head Holes (2.4mm Wise-Lock "L" Distal Radius Dorsal Plate, 2 Head Holes), Material - TI</p> <p>4. L Plate - 3 Head Holes (2.4mm Wise-Lock "L" Distal Radius Dorsal Plate, 3 Head Holes), Material - TI</p>	II b

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	<p>5. L Plate Oblique – 3 Head Holes (2.4mm Wise-Lock "L" Distal Radius Dorsal Plate, Oblique), Material – TI</p> <p>6. Volar Plate – 5 Head Holes (2.4mm Wise - Lock Distal Radius Volar Plate, 5 Head Holes), Material – TI</p> <p>7. Volar plate Extra articular – 5 Head Holes (2.4mm Wise-Lock Distal Radius Volar Plate, Extra-articular, 5 Head Holes), Material – TI</p> <p>8. Volar plate Extra articular – 4 Head Holes (2.4mm Wise-Lock Distal Radius Volar Plate, Extra-articular, 4 Head Holes), Material – TI</p> <p>9. Volar Buttress Plate Juxta articular - 5 Head Holes (2.4mm Wise-Lock Volar Buttress Plate Juxta articular, 5 Head Holes), Material – TI</p> <p>10. Volar Plate Extra Articular/Extra Long – 4 Head holes (2.4mm Wise-Lock Distal Radius Volar Plate, Extra-Long, 4 Head Holes), Material – TI</p> <p>11. Volar Plate Extra Articular/Extra Long – 8 Head Holes (2.4mm Wise-Lock Distal Radius Volar Plate, Extra-Long, 8 Head Holes), Material – TI</p> <p>12. Volar Column Plate (2.4mm Wise-Lock Volar Column Distal Radius Plate, 9 Head Holes), Material – TI</p> <p>13. Proximal Radius Plate for Radial Head Rim – 5 Head Holes (2.4mm Wise-Lock Proximal Radius Plate for Radius Head Rim), Material – TI</p> <p>14. Proximal Radius Plate for Radial Head Neck – 5 Head Holes (2.4mm Wise-Lock Proximal Radius Plate for Radial Head Neck), Material – TI</p> <p>15. Volar Rim Plate (T-Wrist Volar Plate, 7 – Head Holes), Material – TI</p> <p>16. 2.4mm Wise-Lock Screw, Self-Tapping, Length 10mm to 30mm, Material – TI</p> <p>17. 2.4mm Cortical Screws, Self-Tapping, Length 10mm to 30mm, Material – TI</p> <p>18. 2.7mm Cortical Screws, Self-Tapping, Length 10mm to 30mm, Material – TI</p> <p>19. 2.5mm Volar Screw, Self-Tapping, Partial Thread, Length 10mm to 30mm, Material - TI</p> <p>20. 2.5mm Volar Screw, Self-Tapping, Full Thread, Length 10mm to 30mm, Material – TI</p> <p>21. 2.00mm Peg Screw, Length 10mm to 30mm, Material – TI</p> <p>22. Kirschner Wire (K-Wire), Length 130mm to 150mm, Material – TI</p>	
<p>Humerus & Ulna System (Sterile/Non-sterile)</p>	<p>1. 2.7/3.5mm Wise-Lock Dorsolateral Distal Humerus Plate, Material – TI & SS</p> <p>2. 2.7/3.5mm Wise-Lock Dorsolateral Distal Humerus Plate with Lateral Support, Material – TI & SS</p>	<p>II b</p>

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	<p>3. 2.7/3.5mm Wise-Lock Dorsolateral Medial Distal Humerus Plate, Material – TI & SS</p> <p>4. 3.5mm Wise-Lock Extra-Articular Distal Humerus Plate, Material – TI & SS</p> <p>5. PHEELOS-3.5mm Wise-Lock Proximal Humerus Plate - Short, Material – TI & SS</p> <p>6. PHEELOS-3.5mm Wise-Lock Proximal Humerus Plate, Long, Material – TI & SS</p> <p>7. 3.5mm Wise-Lock Proximal Humerus Plate, Material – TI & SS</p> <p>8. 3.5mm Wise-Lock Periarticular Proximal Humerus Plate, Material – TI & SS</p> <p>9. 3.5mm Wise-Lock Metaphyseal Plate for Distal Medial Humerus, Material – TI & SS</p> <p>10. 3.5mm Wise-Lock Olecranon Plate, Material – TI & SS</p> <p>11. 2.7mm Wise-Lock Screw, Self-Tapping, Length – 14mm to 60mm, Material – TI & SS</p> <p>12. 3.5mm Wise-Lock Screw, Self-Tapping, Length – 14mm to 60mm, Material – TI & SS</p> <p>13. 3.5mm Cortical Screw, Self-Tapping, Length – 14mm to 50mm, Material – TI & SS</p>	
<p>Tibia and Fibula system (Locking and Non Locking) (Sterile/Non-sterile)</p>	<p>1. 3.5mm Wise-Lock Medial Distal Tibia Plate, Material – TI & SS</p> <p>2. 3.5mm Wise-Lock Medial Proximal Tibial Plate, Material – TI & SS</p> <p>3. 3.5mm Wise-Lock Posterior Medial Proximal Tibia Plate, Material – TI & SS</p> <p>4. 3.5mm Wise-Lock Anterolateral Distal Tibia Plate, Material – TI & SS</p> <p>5. 3.5mm Wise-Lock Medial Distal Tibia Plate, Without Tab, Material – TI & SS</p> <p>6. 3.5mm Wise-Lock Proximal Tibia Plate, Material – TI & SS</p> <p>7. 3.5mm Wise-Lock Metaphyseal Plate for Medial Distal Tibia, Material – TI & SS</p> <p>8. 4.5mm Wise-Lock Proximal Lateral Tibial Plate, Material – TI & SS</p> <p>9. 4.5mm Wise-Lock Osteotomy Medial High Tibia Plate, Material – TI & SS</p> <p>10. 4.5mm Wise-Lock Osteotomy Lateral High Tibia Plate, Material – TI & SS</p> <p>11. 3.5mm Wise-Lock Pilon Plate, Material – TI & SS</p> <p>12. 3.5mm Wise-Lock Lateral Distal Fibula Plate, Material – TI & SS</p> <p>13. 4.5mm Lateral Tibial Head Buttress Plate, Material – TI & SS</p> <p>14. 2.7mm Wise-Lock Screw, Self-Tapping, Length – 10mm - 60 mm, Material – TI & SS</p>	<p>II b</p>

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	<p>15. 3.5mm Wise-Lock Screw, Self-Tapping, Length – 10mm - 60 mm, Material – TI & SS</p> <p>16. 3.5mm Cortical Screw, Self-Tapping, Length – 10mm - 50 mm, Material – TI & SS</p> <p>17. 5.0mm Wise-Lock Screw, Self-Tapping, Length – 12mm - 90 mm, Material – TI & SS</p> <p>18. 4.5mm Cortical Screw, Self-Tapping, Length – 12mm - 80 mm, Material – TI & SS</p> <p>19. 6.5mm Cancellous Screw, 16mm Thread, Length – 40mm to 120mm, Material – TI & SS</p> <p>20. 6.5mm Cancellous Screw, 32mm Thread, Length – 40mm to 120mm, Material – TI & SS</p> <p>21. 6.5mm Cancellous Screw, Full Thread, Length – 40mm to 120mm, Material – TI & SS</p>	
<p>Femoral System(Locking and Non Locking) (Sterile/Non-sterile)</p>	<p>1. 4.5-5.0mm Wise-Lock Condylar Femoral Plate, Material – TI & SS.</p> <p>2. 4.5-5.0mm Wise-Lock Distal Femur Plate, Material – TI & SS.</p> <p>3. 4.5-5.0mm Wise-Lock Proximal Femoral Plate, Material – TI & SS.</p> <p>4. 4.5-5.0mm Wise-Lock Proximal Femoral Hook Plate, Material – TI & SS.</p> <p>5. 4.5-5.0mm Wise-Lock Osteotomy Lateral Distal Femur Plate, Material – TI & SS.</p> <p>6. 4.5/5.0mm Wise-Lock Osteotomy Medial Distal Femur Plate, Material – TI & SS</p> <p>7. 4.5mm Condylar Buttress Plate, Material – TI & SS</p> <p>8. 5.0mm Wise-Lock Screw, Self-Tapping, Length - 12mm to 90mm, Material – TI & SS</p> <p>9. 4.5mm Cortical Screw, Self-Tapping, Length – 12mm to 80mm, Material – TI & SS</p> <p>10. 6.5mm Cancellous Screw, 16mm Thread, Length – 25mm to 120mm, Material – TI & SS</p> <p>11. 6.5mm Cancellous Screw, 32mm Thread, Length – 40mm to 120mm, Material – TI & SS</p> <p>12. 6.5mm Cancellous Screw, Full Thread, Length - 25mm to 120mm, Material – TI & SS</p> <p>13. 7.3mm Cannulated Screw, 16mm Thread, Length - 30mm to 150mm, Material – TI & SS</p> <p>14. 7.3mm Cannulated Screw, 32mm Thread, Length - 45mm to 150mm, Material – TI & SS</p> <p>15. 7.3mm Cannulated Screw, Full thread, Length - 20mm to 130mm, Material – TI & SS</p>	<p>II b</p>
<p>Variable Angle Plate System (Sterile/Non-sterile)</p>	<p>1. 2.4mm Wise-Lock Variable Angle Two-Column Volar Distal Radius Plate, Narrow, 6 Head Holes, Length - 19.5mm, Material – TI</p> <p>2. 2.4mm Wise-Lock Variable Angle Two-Column Volar Distal Radius Plate, 6 Head Holes, Length – 22mm, Material – TI</p>	<p>II b</p>

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	<ol style="list-style-type: none"> 3. 2.4mm Wise-Lock Variable Angle Two-Column Volar Distal Radius Plate, 7 Head Holes, 25.5mm, Material –TI 4. 2.4mm Wise-Lock Variable Angle Volar Rim Distal Radius Plate, 6 Head Holes, Material –TI 5. 2.7/3.5mm Wise-Lock Variable Angle Dorsolateral Distal Humerus Plate, Material –TI & SS 6. 2.7/3.5mm Wise-Lock Variable Angle Dorsolateral Distal Humerus Plate with Lateral Extension, Material –TI & SS 7. 2.4mm Wise-Lock Variable Angle Screws, Self-Tapping, (Star Head), Length – 06mm to 30mm, Material – TI & SS 8. 2.4mm Wise Lock Screw, Self-tapping, Length – 06mm to 30mm, Material – TI 9. 2.7mm Cortical Screws, Self-Tapping, Length - 10to 30mm, Material – TI 10. 2.7mm Wise-Lock Variable Angle Screws, Self-Tapping, (Star Head), Length – 06mm to 30mm, Material – TI & SS 11. 3.5mm Wise-Lock Screw, Self-Tapping, Length – 12mm to 60mm, Material – TI & SS 12. 3.5mm Cortical Screw, Self-Tapping, Length – 14mm to 60mm, Material – TI & SS 	
Austin Moore Hip Prosthesis (Sterile/Non-sterile)	<ol style="list-style-type: none"> 1. Austin Moore Hip Prosthesis - Standard Stem, Head Dia. 38mm to 55mm, Material – SS 	II b
Thompson Hip Prosthesis (Sterile/Non-sterile)	<ol style="list-style-type: none"> 1. Thompson Hip Prosthesis - Standard Stem, Head Dia. 38mm to 55mm, Material – SS 	II b

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Auxein Medical Private Limited	Plot No. 168-169-170, Phase-IV, Kundli Industrial Area, HSIIDC, Sector-57, Sonapat, Haryana – 131028, India

EU Representative

CMC Medical Devices & Drugs S.L. C/Horacio Lengo No 18, CP 29006, Málaga, Spain

TEL: +34951214054, FAX: +34952330100, info@cmcmedicaldevices.es

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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