



EU Quality Management System Certificate

Certificate no.:
C721730

Initial certification date:
17 October 2024

Valid Until:
16 October 2029

This is to certify that the quality system of

Auxein Medical Private Limited

Plot No. 168-169-170, Phase-4, Kundli Industrial Area,
HSIIDC, Sector-57, Sonapat - 131028, Haryana, India

SRN: IN-MF-000018837

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

Sterile and Non Sterile Orthopedic Implants

Has been assessed and found to comply with respect to:

The conformity assessment procedure described in Annex IX, (Chapter I & III) of Regulation (EU) 2017/745 on Medical Devices

Place and date:
Høvik, 10 November 2025



For the issuing office:
DNV Product Assurance AS – Notified Body 2460
Veritasveien 1, 1363 Høvik, Norway

Menaka Singh
Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

NOTIFIED BODY 2460: DNV Product Assurance AS, Veritasveien 1, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com

MDR-CO-078-A V0.8

Jurisdiction

Application of Regulation 2017/745 on medical devices, implemented in Norway by Act 7 May 2020 no. 37 on medical devices and Regulation 9 May 2021 no.1476 on medical devices by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Report No.	Issue Date
0.0	Original Certificate	2994841	17 October 2024
1.0	Addition of Foot Plate System, Radius Plate System, and Humerus Plate System	2994841	23 March 2024
2.0	Addition of Shoulder Arthroscopy System and Knee Arthroscopy System	2994836 2994917	10 November 2025

Products covered by this Certificate:

Product Description (and intended purpose for class IIb)	Product Name	Class*
<p>Femur Nailing System (Sterile/Non-Sterile)</p> <p>The femur nail system is intended to Stabilize Femoral shaft fractures, Trochanteric Fractures, Ipsilateral Neck and Femoral Head, Impending Pathologic Fractures, Nonunions and Malunions of femur bone.</p>	<ol style="list-style-type: none"> AJAX Advance Nail, Short and Long (Left/Right), Titanium with <ul style="list-style-type: none"> AJAX 4.9mm Locking Bolt, Self-Tapping, Titanium AJAX Blade, Titanium AJAX Nail End Cap (For Ajax Blade), Titanium AJAX Nail End Cap (For Cephalic Screw), Titanium Inner Screw for Ajax Cephalic Screw, Titanium AJAX Cephalic Screw, Titanium End Cap for Ajax Cephalic Screw, Titanium Expert Femur Nail, Left/Right, Stainless Steel/Titanium with <ul style="list-style-type: none"> End Caps for Expert Femur Nail, Stainless Steel/Titanium Ø4.8mm Locking Bolt, Self-Tapping, For Expert Femur Nail, Stainless Steel/Titanium Ø6.4mm Cannulated Anti-Rotation Screw, Self-Tapping, For Expert Femur Nail, Stainless Steel/Titanium Retrograde Femur Nail, Stainless Steel/Titanium with 	IIb

	<ul style="list-style-type: none"> ○ 5.0mm Locking Screw for Retrograde Femur Nail, Stainless Steel/Titanium ○ End Cap for Retrograde Femur Nail, Stainless Steel/Titanium <p>4. ATHOS Nail, Stainless Steel/Titanium following Variants</p> <ul style="list-style-type: none"> ○ 125° Athos Nail Type-II, Short, Stainless Steel/Titanium ○ 125° Athos Nail Type-II, Long, Left/Right, Stainless Steel/Titanium ○ 130° Athos Nail Type-II, Short, Stainless Steel/Titanium ○ 130° Athos Nail Type-II, Long, Left/Right, Stainless Steel/Titanium ○ 125° Anti-Rotation Athos Nail, Short, Stainless Steel/Titanium ○ 125° Anti-Rotation Athos Nail, Long, Left/Right, Stainless Steel/Titanium ○ 130° Anti-Rotation Athos Nail, Short, Stainless Steel/Titanium ○ 130° Anti-Rotation Athos Nail, Long, Left/Right, Stainless Steel/Titanium <p>With following accessories</p> <ul style="list-style-type: none"> ○ End Cap for Athos Nail Type-II, Stainless Steel/Titanium ○ Inner Screw for Athos Nail Type-II, Stainless Steel/Titanium ○ Ø10.5mm Cephalic Screw, For Athos Nail, Stainless Steel/Titanium ○ End Cap For Ø10.5mm Cephalic Screw for Athos Nail, Stainless Steel/Titanium ○ Ø4.8mm Locking Bolt, Self-Tapping, For Athos Nail, Stainless Steel/Titanium ○ End Cap for Anti-Rotation Athos Nail, Stainless Steel/Titanium ○ Inner Screw for Anti-Rotation Athos Nail-Long (For Cephalic Screw), Stainless Steel/Titanium ○ Inner Screw for Anti-Rotation Athos Nail-Short (For Anti-Rotation Screw), Stainless Steel/Titanium 	
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	<p>Steel/Titanium</p> <ul style="list-style-type: none"> ○ Ø6.4mm Cannulated Anti-Rotation Screw for Athos Nail, Stainless Steel/Titanium ○ Ø10.5mm Cephalic Screw, For Athos Nail, Stainless Steel/Titanium <p>5. JIN-Type Femur Nail, Stainless Steel/Titanium with</p> <ul style="list-style-type: none"> ○ End Cap for JIN Type - Femur Nail, Stainless Steel/Titanium ○ Ø4.5mm Locking Bolt, Self-Tapping, For JIN Type – Femur Nail, Stainless Steel/Titanium <p>6. KONZEPT Femur Nail also known as Universal Intramedullary Cannulated Femur Nail, Left/Right, Stainless Steel/Titanium with</p> <ul style="list-style-type: none"> ○ End Cap for Universal Intramedullary Cannulated Femur Nail M10 X 1, Stainless Steel/Titanium ○ Compression Screw for Universal Intramedullary Cannulated Femur Nail, Stainless Steel/Titanium ○ 4.5mm Locking Bolt for Universal Intramedullary Cannulated Femur Nail, Stainless Steel/Titanium ○ 6.5mm Cannulated Reconstruction Screw for Universal Intramedullary Cannulated Femur Nail, Stainless Steel/Titanium ○ 6.5mm Locking Bolt for Universal Intramedullary Cannulated Femur Nail, Full Thread, Stainless Steel/Titanium ○ 6.5mm Blocking set for Universal Intramedullary Cannulated Femur Nail, Stainless Steel/Titanium 	
<p>Tibia Plate System (Sterile/Non-Sterile)</p> <p>Device is intended to treat Non-union, Malunions and fracture of tibia bone.</p>	<p>Tibia Plates: (Stainless steel and Titanium), Left/Right</p> <ul style="list-style-type: none"> ○ 3.5mm AV-Wiselock Proximal Tibia Plate, Small Bend ○ 3.5mm AV-Wiselock Proximal Tibia Plate, Large Bend ○ 3.5mm AV-Wiselock Medial 	<p>IIb</p>

	<p>Proximal Tibia Plate</p> <ul style="list-style-type: none"> ○ 4.5/5.0mm AV-Wiselock Proximal Lateral Tibia Plate ○ 3.5mm Wise-Lock Medial Distal Tibia Plate ○ 3.5mm Wise-Lock Proximal Tibia Plate ○ 3.5mm Wise-Lock Medial Proximal Tibia Plate ○ 3.5mm Wise-Lock Posterior Medial Proximal Tibia Plate ○ 3.5mm Wise-Lock Anterolateral Distal Tibia Plate ○ 3.5mm Wise-Lock Medial Distal Tibia Plate, Without Tab ○ 3.5mm Wise-Lock Low Profile Medial Distal Tibia Plate, Without Tab ○ 3.5mm Wise-Lock Metaphyseal Plate for Medial Distal Tibia ○ 3.5mm Wise-Lock Pilon Plate ○ 3.5mm Wise-Lock Pilon Plate, Cruciform ○ 3.5mm Wise-Lock Small Dynamic Compression Plate with LC Under Cuts ○ 3.5mm Wise-Lock Hook Plate ○ 3.5mm Wise-Lock Cloverleaf Plate ○ 4.5/5.0mm Wise-Lock Proximal Lateral Tibia Plate ○ 4.5/5.0mm Wise-Lock Medial Proximal Tibia Plate ○ 4.5/5.0mm Wise-Lock Proximal Tibia Plate ○ 4.5/5.0mm Wise-Lock "L" Buttress Plate ○ 4.5/5.0mm Wise-Lock "T" Buttress Plate ○ 4.5/5.0mm Wise-Lock "T" Plate ○ 4.5/5.0mm Wise-Lock Osteotomy Medial High Tibia Plate ○ 4.5/5.0mm Wise-Lock Osteotomy Lateral High Tibia Plate ○ 5.0mm Wise-Lock Proximal Lateral 	
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	<p>Tibia Plate (LISS)</p> <ul style="list-style-type: none"> ○ 3.5mm Small Dynamic Compression Plate ○ 3.5mm Small Limited Contact Dynamic Compression Plate ○ 3.5mm Cloverleaf ○ 3.5mm Hook Plate ○ 4.5mm Lateral Tibial Head Buttress Plate ○ 4.5mm Proximal Tibia Medial Plate ○ 4.5mm Proximal Tibia Plate with Round Holes ○ 4.5mm Proximal Lateral Tibia Plate ○ 4.5mm Distal Tibia Plate ○ 4.5mm Distal Lateral Tibia Plate with Round Holes ○ 4.5mm Distal Tibia Lateral Plate ○ 4.5mm Fibular Distal Tibia Plate ○ 4.5mm "T" Plate ○ 4.5mm "T" Buttress Plate ○ 4.5mm "L" Buttress Plate ○ 4.5mm Hook Plate <p>Bone Screws: (Stainless steel and Titanium)</p> <ul style="list-style-type: none"> ○ 2.7mm Wise-Lock Screw, Self-Tapping (Hex Head) ○ 3.5mm AV-Wiselock Screw, Self-Tapping ○ 3.5mm Cortical Screw, Self-Tapping (Star Head) ○ 3.5mm Wise-Lock Screw, Self-Tapping (Hex Head) ○ 3.5mm Wise-Lock Screw, Self-Drilling, (Hex Head) ○ 3.5mm Wise-Lock Cancellous Screw, Full Thread, Self-Tapping, (Hex Head) ○ 3.5mm Wise-Lock Cancellous Screw, Short Thread, Self-Tapping, (Hex Head) ○ 3.5mm Cortical Screw, Self-Tapping, (Hex Head) ○ 3.5mm Cortical Screw, (Hex Head) 	
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	<ul style="list-style-type: none"> ○ 3.5mm Cancellous Screw, Short Thread ○ 3.5mm Cancellous Screw, Full Thread ○ 4.0mm Cancellous Screw, Short Thread ○ 4.0mm Cancellous Screw, Full Thread ○ 4.5mm Cortical Screw, Self-Tapping, (Star Head) ○ 4.5mm Cortical Screw, (Hex Head) ○ 5.0mm AV-Wiselock Screw, Self-Tapping, (Star Head) ○ 5.0mm Wise-Lock Screw, Self-Tapping, (Hex Head) ○ 5.0mm Wise-Lock Screw, Self-Tapping & Self-Drilling, (Hex Head) ○ 5.0mm Wise-Lock Cancellous Screw, Full Thread, Self-Tapping, (Hex Head) ○ 5.0mm Wise-Lock Cancellous Screw, Short Thread, Self-Tapping, (Hex Head) ○ 5.0mm Wise-Lock Cannulated Screw, Full Thread, Self-Tapping ○ 5.0mm Wise-Lock Cannulated Screw, Partial Thread, Self-Tapping ○ 6.5mm Cancellous Screw, 16mm Thread ○ 6.5mm Cancellous Screw, 32mm Thread ○ 6.5mm Cancellous Screw, Full Thread ○ Washer for Small Fragment Screws ○ Washers for Large Fragment Screws 	
<p>Foot Plate System (Sterile/Non-Sterile) The Foot Plate System is intended to treat Non-union, Malunions and fracture of foot bone</p>	<p>Foot Plate System: (Stainless steel and Titanium), Left/Right</p> <ul style="list-style-type: none"> ○ Ø2.7mm-6.0mm Metatarsal Shortening Implant ○ 2.4mm AV-Wiselock Endosteal 	<p>IIb</p>

	<p>Plate, Standard, Left/Right, Titanium</p> <ul style="list-style-type: none"> ○ 2.4mm AV-Wiselock Endosteal Plate, Curved, Left/Right, Titanium ○ 2.7mm AV-Wiselock MTP Fusion M Plate, 0°/5°/10° Dorsiflexion, Left/Right, Stainless Steel/Titanium ○ 2.7mm AV-Wiselock MTP Revision M Plate, 5°/10° Dorsiflexion, Left/Right, Stainless Steel/Titanium ○ 2.7mm AV-Wiselock TMT-I Medial Fusion M Plate, Left/Right, Stainless Steel/Titanium ○ 2.7mm AV-Wiselock TMT-I Plantar Fusion M Plate, Left/Right, Stainless Steel/Titanium ○ 3.5mm AV-Wiselock Calcaneus M Plate, Small/Medium/Large, Left/Right, Stainless Steel/Titanium ○ 3.5mm AV-Wiselock Medial Column Fusion Plate, Left/Right, Stainless Steel/Titanium ○ 3.5mm AV-Wiselock Medial Column Fusion Plate, Talus Extension, Left/Right, Stainless Steel/Titanium ○ 3.5mm AV-Wiselock Medial Column Fusion Plantar Plate, Left/Right, Stainless Steel/Titanium ○ 3.5mm AV-Wiselock MIS Calcaneal Plate Type-III, 	
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	<p>Left/Right, Stainless Steel/Titanium</p> <ul style="list-style-type: none"> ○ 3.5mm AV-Wiselock Plantar Lapidus Plate, Left/Right, Stainless Steel/Titanium ○ 3.5mm AV-Wiselock Plantar Lapidus Plate, Short, Left/Right, Stainless Steel/Titanium ○ 2.7mm Wise-Lock Plate, Straight, titanium ○ 2.7mm Wise-Lock Condylar Plate, titanium ○ 2.7mm Wise-Lock T-Plate titanium ○ 2.7mm Wise-Lock L-Plate, Left/Right, Titanium ○ 2.7mm Wise-Lock L-Plate, Oblique, Left/Right, Titanium ○ 2.7mm Mini Condylar Plate, Left/Right, Titanium ○ 2.7mm Wise-Lock Straight Plate, titanium ○ 2.4/2.7mm Wise-Lock X-Plate, titanium ○ 2.7mm Wise-Lock X-Plate, (Small/Medium/Large), Stainless Steel/Titanium ○ 2.7mm Wise-Lock Straight Plate with Single Start Thread, Stainless Steel/Titanium ○ 3.5mm Wise-Lock Calcaneal Plate, Left/Right, Stainless Steel/Titanium ○ 3.5mm Wise-Lock Calcaneal Plate Type-I, Left/Right, Stainless 	
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	<p>Steel/Titanium</p> <ul style="list-style-type: none"> ○ 3.5mm Wise-Lock Calcaneal Plate Type-II, Left/Right, Stainless Steel/Titanium ○ 3.5mm Wise-Lock Calcaneal Plate Type-III, Left/Right, Stainless Steel/Titanium ○ 3.5mm Wise-Lock Calcaneal Plate Type-IV, Left/Right, Stainless Steel/Titanium ○ 3.5mm Wise-Lock Calcaneal Plate Type-V, Left/Right, Stainless Steel/Titanium ○ 2.7mm Mini "L" Plate, Left/Right, Stainless Steel/Titanium ○ 2.7mm "T" Plate, Stainless Steel/Titanium ○ 2.7mm Quarter Tubular Plate, Stainless Steel/Titanium ○ 2.7mm Dynamic Compression Plate, Stainless Steel/Titanium ○ 2.7mm Reconstruction Plate, Straight, Stainless Steel/Titanium ○ 3.5mm Calcaneal Plate, Stainless Steel/Titanium ○ 2.0mm Cortical Screw, Self-Tapping, (Star Head), Titanium ○ 2.4mm Cortical Screw, Self-Tapping, (Star Head), Titanium ○ 2.4mm Variable Angle Screws, Self-Tapping, (Star Head), Titanium ○ 2.7mm Cortical Screw, Self-Tapping, (Star Head), Stainless 	
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	<p>Steel/Titanium</p> <ul style="list-style-type: none"> ○ 2.7mm AV-Wiselock Screw, Self-Tapping, (Star Head), Stainless Steel/Titanium ○ 2.7mm Wise-Lock Screw, Self-Tapping, (Star Head), Stainless Steel/Titanium ○ 4.0mm Cancellous Screw, Short Thread, Stainless Steel/Titanium, ○ 3.5mm AV-Wiselock Screw, Self-Tapping, Titanium/Stainless Steel ○ 3.5mm Wise-Lock Screw, Self-Tapping, (Star Head), Titanium/Stainless Steel ○ 3.5mm Cortical Screw, Self-Tapping, (Star Head), Titanium/Stainless Steel ○ 2.7mm Cortical Screw, Self-Tapping, (Star Head), Titanium ○ 2.7mm Wise-Lock Screw, Self-Tapping, (Star Head), Titanium ○ 2.7mm Wise-Lock Screw, Self-Tapping (Hex Head), Stainless Steel/Titanium ○ 3.5mm Wise-Lock Screw, Self-Tapping, (Hex Head), Stainless Steel/Titanium ○ 3.5mm Wise-Lock Screw, Self-Drilling, (Hex Head), Stainless Steel/Titanium ○ 3.5mm Wise-Lock Cancellous Screw, Full Thread, Self-Tapping, (Hex Head), Stainless Steel/Titanium ○ 3.5mm Wise-Lock Cancellous Screw, Short Thread, Self- 	
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	<p>Tapping, (Hex Head), Stainless Steel/Titanium</p> <ul style="list-style-type: none"> ○ 3.5mm Cortical Screw, Self-Tapping, (Hex Head), Stainless Steel/Titanium, ○ 2.7mm Cortical Screw, (Hex Head), Stainless Steel/Titanium ○ 2.7mm Cortical Screw, Self-Tapping, (Hex Head), Stainless Steel/Titanium ○ Tarsus Screw, Titanium ○ 2.5mm Cannulated Herbert Screw, Short Thread, (Star Head), Titanium ○ 2.5mm Cannulated Herbert Screw, Long Thread, (Star Head), Titanium ○ 3.0mm Cannulated Herbert Screw, Short Thread, (Star Head), Titanium ○ 3.0mm Cannulated Herbert Screw, Long Thread, (Star Head), Titanium ○ Herbert Screw (Hex Head), 3.0/3.9mm Cannulated Compression Screw ○ 2.5mm Headless Cannulated Screw, Micro, Titanium ○ 3.5mm Headless Cannulated Screw, Mini, Titanium ○ 4.0mm Headless Cannulated Screw, Standard, Titanium ○ 4.7mm Headless Cannulated Screw, Titanium ○ 5.5mm Headless Cannulated 	
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	<p>Screw, Titanium</p> <ul style="list-style-type: none"> ○ 7.5mm Headless Cannulated Screw ○ 3.0mm Cannulated Cancellous Screw ○ 3.5mm Cannulated Cortical Screw ○ 4.0mm Cannulated Cancellous Screw ○ 4.5mm Cannulated Cortical Screw 	
<p>Radius Plate System (Sterile/Non-Sterile) The Radius Plate System is intended to treat Non-union, Malunions and fracture of Radius bone.</p>	<p>Radius Plate System: (Stainless steel and Titanium), Left/Right</p> <ul style="list-style-type: none"> ○ 2.4mm Variable Angle Two-Column Volar Distal Radius Plate, Left/Right, Titanium/Stainless Steel Shaft Holes: 2 to 8 Width (mm): 19.5, 22, 25.5 Head Holes: 6, 7 Available in: Narrow, Standard, Wide ○ 2.4mm AV-Wiselock Distal Radius Volar Plate, Extra-articular, Left/Right, Titanium/Stainless Steel Head Holes: 4, 5 Shaft Holes: 3, 5 ○ 2.4mm AV-Wiselock Dorsal Distal Radius Plate, Radial Column, Titanium/Stainless Steel Shaft Holes: 5, 6 ○ 2.4mm AV-Wiselock Dorsal Distal Radius Plate, Intermediate Column, Titanium/Stainless Steel Head Holes: 2 Shaft Holes: 3, 4 ○ 2.4mm AV-Wiselock "L" Dorsal Distal Radius Plate, Titanium/Stainless Steel, Left/Right Head Holes: 2, 3 Shaft Holes: 3, 5 	<p>IIb</p>

	<ul style="list-style-type: none"> ○ 2.4mm AV-Wiselock "L" Dorsal Distal Radius Plate, Oblique, Titanium/Stainless Steel, Left/Right Head Holes: 3 Shaft Holes: 3, 5 ○ 2.4mm AV-Wiselock "T" Dorsal Distal Radius Plate, Titanium/Stainless Steel, Left/Right Head Holes: 3 Shaft Holes: 3, 5 ○ 2.4mm Variable Angle Volar Rim Distal Radius Plate, Left/Right, Titanium/Stainless Steel Shaft Holes: 3 to 8 Head Holes: 6, 7 ○ 2.4mm AV-Wiselock Distal Radius Small Fragment M Plate, Curved, Left/Right, Titanium/Stainless Steel Shaft Holes: 5 ○ 2.4mm AV-Wiselock T-Distal Radius Small Fragment M Plate, Left/Right, Titanium/Stainless Steel Shaft Holes: 7 ○ 2.4mm AV-Wiselock L-Distal Radius Small Fragment M Plate, Left/Right, Titanium/Stainless Steel Shaft Holes: 8 ○ 2.4mm AV-Wiselock Lateral Distal Radius Small Fragment M Plate, Titanium/Stainless Steel Shaft Holes: 6 ○ 2.4mm AV-Wiselock Distal Radius Volar Rim M Plate, Left/Right, Titanium/Stainless Steel Shaft Holes: 13 ○ 2.4mm AV-Wiselock Volar Lunate Facet M Plate, Left/Right, Titanium/Stainless Steel 	
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	<p>Shaft Holes: 7</p> <ul style="list-style-type: none"> ○ 2.4mm AV-Wiselock Dorsal H-Distal Radius M Plate, Left/Right, Titanium/Stainless Steel Shaft Holes: 12 ○ 2.4mm AV-Wiselock Dorsal Frame Distal Radius M Plate, Narrow, Left/Right, Titanium/Stainless Steel Shaft Holes: 18 ○ 2.4mm AV-Wiselock Dorsal Frame Distal Radius M Plate, Left/Right, Titanium/Stainless Steel Shaft Holes: 20 ○ 2.4mm AV-Wiselock Volar Distal Radius M Plate, XL, Left/Right, Titanium/Stainless Steel Shaft Holes: 17, 20, 24 ○ 2.4mm AV-Wiselock Volar Distal Radius Fracture M Plate, Left/Right, Titanium/Stainless Steel Shaft Holes: 11 ○ 2.4mm AV-Wiselock Volar Distal Radius Fracture M Plate, Narrow, Left/Right, Titanium/Stainless Steel Shaft Holes: 10 ○ 2.4mm AV-Wiselock Distal Ulna M Plate, Titanium/Stainless Steel Shaft Holes: 7, 10 ○ 2.4mm AV-Wiselock FPL Volar Distal Radius M Plate, Left/Right, Titanium/Stainless Steel Shaft Holes: 10 ○ 2.4mm AV-Wiselock FPL Volar Distal Radius M Plate, Long, Left/Right, Titanium/Stainless Steel Shaft Holes: 12 ○ 2.4mm Wise-Lock Distal Radius 	
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	<p>Dorsal Plate, Straight, Titanium Shaft Holes: 5, 6</p> <ul style="list-style-type: none"> ○ 2.4mm Wise-Lock "T" Distal Radius Dorsal Plate, Titanium Shaft Holes: 3, 4 Head Holes: 3 ○ 2.4mm Wise-Lock "L" Distal Radius Dorsal Plate, Left/Right, Titanium Shaft Holes: 3, 4 Head Holes: 2, 3 ○ 2.4mm Wise-Lock "L" Distal Radius Dorsal Plate, Oblique, Left/Right, Titanium Shaft Holes: 3, 4 ○ 2.4mm Wise-Lock Distal Radius Volar Plate, Left/Right, Titanium Shaft Holes: 3, 5 Head Holes: 5 ○ 2.4mm Wise-Lock Distal Radius Volar Plate, Extra-Articular, Left/Right, Titanium Shaft Holes: 3, 5 Head Holes: 4, 5 ○ 2.4mm Wise-Lock Volar Column Distal Radius Plate, Left/Right, Titanium Shaft Holes: 3, 4, 5 Head Holes: 8 ○ 2.4mm Wise-Lock Volar Column Distal Radius Plate, Left/Right, Extra articular, Titanium Shaft Holes: 3, 4, 5 Head Holes: 9 ○ 2.4mm Wise-Lock Volar Buttress Plate, Left/Right, Titanium Shaft Holes: 3 Head Holes: 5 ○ 2.4mm Wise-Lock Distal Radius 	
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	<p>Volar Plate, Extra-Long, Left/Right, Titanium Shaft Holes: 8, 10, 12 Head Holes: 4</p> <ul style="list-style-type: none"> ○ 2.4mm Wise-Lock Proximal Radius Plate for Radial Head Rim, Left/Right, Titanium Shaft Holes: 2, 3, 4 Head Holes: 5 ○ 2.4mm Wise-Lock Proximal Radius Plate for Radial Head Neck, Titanium Shaft Holes: 2, 3, 4 Head Holes: 5 ○ 2.5mm Wise-Lock "T" Wrist Volar Plate, Left/Right, Titanium Shaft Holes: 3 to 12 Head Holes: 7 ○ Distal Radius Plate, Stainless Steel/Titanium Shaft Holes: 2 to 6 ○ 2.4mm Variable Angle Screw, Self-Tapping, (Star Head), Titanium/Stainless Steel Length (mm): 6 to 30 ○ 2.4mm Wise-Lock Screw, Self-Tapping, (Star Head), Titanium/Stainless Steel Length (mm): 6 to 30 ○ 2.4mm Cortical Screw, Self-Tapping, (Star Head), Titanium/Stainless Steel Length (mm): 8 to 34 ○ 2.7mm Cortical Screw, Self-Tapping, (Star Head), Titanium/Stainless Steel Length (mm): 6 to 30 ○ 1.8mm Buttress Screws, (Star 	
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	<p>Head), Length 12mm, Stainless Steel/Titanium Length (mm): 12 to 24</p> <ul style="list-style-type: none"> ○ 2.5mm Volar Screw, Self-Tapping, Full Thread, Titanium Length (mm): 10 to 30 ○ 2.5mm Volar Screw, Self-Tapping, Partial Thread, Titanium Length (mm): 10 to 30 ○ 2.0mm Peg Screw, Titanium Length (mm): 10 to 30 ○ 2.4mm Cortical Screw, Self-Tapping, (Hex Head), Titanium Length (mm): 6 to 30 ○ 2.4mm Wise-Lock Screw, Self-Tapping, (Hex Head), Titanium Length (mm): 6 to 30 ○ 2.7mm Cortical Screw, Self-Tapping, (Hex Head), Titanium Length (mm): 6 to 30 	
<p>Humerus Plate System (Sterile/Non-Sterile) The Humerus Plate System is intended to treat Non-union, Malunions and fracture of Humerus bone.</p>	<p>Humerus Plate System: (Stainless steel and Titanium), Left/Right</p> <ul style="list-style-type: none"> ○ Pheelos-3.5mm AV-Wiselock Proximal Humerus Plate with Suture Cuts, Short and Long, Titanium/Stainless Steel ○ Pheelos - 3.5mm Wise-Lock Proximal Humerus Plate, Short and Long, Titanium/Stainless Steel ○ 3.5mm Wise-Lock Periarticular Proximal Humerus Plate, Titanium/Stainless Steel ○ 3.5mm Wise-Lock Proximal Humerus Plate, Titanium/Stainless Steel ○ 3.5mm Small "T" Plate, Right 	<p>IIb</p>

	<p>Angled, Titanium/Stainless Steel</p> <ul style="list-style-type: none"> ○ 3.5mm Small "T" Plate, Oblique Angled, Titanium/Stainless Steel ○ 3.5mm Wise-Lock Small "T" Plate, Titanium/Stainless Steel ○ 3.5mm Wise-Lock Small "T" Plate, Oblique Angled, Titanium/Stainless Steel ○ Proximal Humeral Plate, Titanium/Stainless Steel, Titanium/Stainless Steel ○ 3.5mm AV-Wiselock Extra-Articular Distal Humerus Plate, Titanium/Stainless Steel ○ 2.7/3.5mm Wise-Lock Dorsolateral Distal Humerus Plate, Titanium/Stainless Steel ○ 2.7/3.5mm Wise-Lock Dorsolateral Distal Humerus Plate with Lateral Support, Titanium/Stainless Steel ○ 2.7/3.5mm Wise-Lock Dorsolateral Medial Distal Humerus Plate, Titanium/Stainless Steel ○ 3.5mm Wise-Lock Extra-Articular Distal Humerus Plate, Titanium/Stainless Steel ○ 3.5mm Wise-Lock Metaphyseal Plate for Distal Medial Humerus, Titanium/Stainless Steel ○ 3.5mm Wise-Lock Metaphyseal Plate, Titanium/Stainless Steel ○ 3.5/4.5mm Wise-Lock Metaphyseal Plate, Titanium/Stainless Steel ○ 3.5mm Y-Reconstruction Plate, Titanium/Stainless Steel ○ Y-Fork Plate, Titanium/Stainless 	
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	<p>Steel</p> <ul style="list-style-type: none"> ○ Distal Lateral Humeral Plate, Titanium/Stainless Steel ○ Lecestre Plate, Titanium/Stainless Steel ○ 2.7/3.5mm AV-Wiselock Dorsolateral Distal Humerus Plate with Lateral Support, Titanium/Stainless Steel ○ 2.7/3.5mm AV-Wiselock Dorsolateral Distal Humerus Plate, Titanium/Stainless Steel ○ 2.7/3.5mm AV-Wiselock Medial Distal Humerus Plate, Titanium/Stainless Steel ○ 2.7/3.5mm AV-Wiselock Extended Medial Distal Humerus Plate, Titanium/Stainless Steel ○ 2.7/3.5mm AV-Wiselock Lateral Distal Humerus Plate, Titanium/Stainless Steel ○ 2.7/3.5mm AV-Wiselock Proximal Olecranon Plate, Titanium/Stainless Steel ○ 2.7/3.5mm AV-Wiselock Olecranon Plate, Titanium/Stainless Steel ○ 2.7/3.5mm AV-Wiselock Extra Articular Proximal Ulna Plate, Titanium/Stainless Steel ○ 2.7mm AV-Wiselock Olecranon Tension M Plate, Titanium/Stainless Steel ○ 2.7mm AV-Wiselock Medial Distal Humerus M Plate, Long, Titanium/Stainless Steel ○ 2.7mm AV-Wiselock Medial Distal Humerus M Plate, Medium, Titanium/Stainless Steel 	
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	<ul style="list-style-type: none"> ○ 2.7mm AV-Wiselock Medial Distal Humerus M Plate, Short, Titanium/Stainless Steel ○ 2.7mm AV-Wiselock Lateral Distal Humerus M Plate, Long, Titanium/Stainless Steel ○ 2.7mm AV-Wiselock Lateral Distal Humerus M Plate, Medium, Titanium/Stainless Steel ○ 2.7mm AV-Wiselock Lateral Distal Humerus M Plate, Short, Titanium/Stainless Steel ○ 3.5mm Wise-Lock Screw, Self-Tapping, (Star Head) ○ 3.5mm Cortical Screw, Self-Tapping, (Star Head) ○ 3.5mm Malleolar Screw ○ Washer for Small Fragment Screw ○ 2.7mm Wise-Lock Screw, Self-Tapping (Hex Head) ○ 3.5mm Wise-Lock Screw, Self-Tapping (Hex Head) ○ 3.5mm Wise-Lock Screw, Self-Drilling, (Hex Head) ○ 3.5mm Wise-Lock Cancellous Screw, Full Thread, Self-Tapping, (Hex Head) ○ 3.5mm Wise-Lock Cancellous Screw, Short Thread, Self-Tapping, (Hex Head) ○ 3.5mm Cortical Screw, Self-Tapping, (Hex Head) ○ 4.0mm Cancellous Screw, Short Thread ○ 4.0mm Cancellous Screw, Full Thread ○ 3.5mm Cortical Screw, (Hex 	
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	<p>Head)</p> <ul style="list-style-type: none"> ○ 3.5mm Cancellous Screw, Short Thread ○ 3.5mm Cancellous Screw, Full Thread 	
<p>Components of shoulder arthroscopy system (sterile)</p> <p>Components of Shoulder Arthroscopy System is indicated for use in the fixation of muscles, ligaments and tendon in patients requiring muscle, ligament or tendon repair</p>	<ul style="list-style-type: none"> ○ Titanium Screw-in Anchor with Needle ○ Titanium Screw-in Anchor without Needle ○ PEEK OPTIMA Screw In Anchor With Needle ○ PEEK CF Screw In Anchor With Needle ○ PEEK OPTIMA Screw In Anchor Without Needle ○ PEEK CF Screw In Anchor Without Needle ○ PEEK OPTIMA AuxPik Suture-Based Anchor ○ PEEK CF Knotless Anchor with Driver ○ PEEK CF Knotless Anchor without Driver ○ Rotador PEEK CF Screw In Knotless Anchor ○ PEEK CF Push In Anchor Without Needle ○ PEEK CF Push In Anchor with Needle ○ Rotador PEEK OPTIMA Screw In Knotless Anchor ○ PEEK OPTIMA Knotless Anchor with Driver ○ PEEK OPTIMA Knotless Anchor ○ PEEK OPTIMA Push In Anchor without Needle 	<p>IIb</p>

	<ul style="list-style-type: none"> ○ PEEK OPTIMA Push In Anchor with Needle ○ Auxsuture Anchor without Needle ○ Auxsuture Anchor with Needle ○ PEEK OPTIMA Tendo Screw-In Anchor ○ PEEK CF Tendo Screw-In Anchor ○ AC Joint Button ○ Gyrolock PEEK OPTIMA Knotless Screw In Anchor ○ Gyrolock SP PEEK OPTIMA Knotless Screw In Anchor 	
<p>Components of Knee arthroscopy system (sterile)</p>	<ul style="list-style-type: none"> ○ Naked Button ○ Adjustable Loop Button ○ Mini Loop Button ○ Large Loop Button ○ Button Extender ○ AUXILOCK® GFS No-Button Adjustable Loop ○ AUXILOCK® GFS Concave Button ○ PEEK CF Interference Screw ○ PEEK OPTIMA Interference Screw ○ Titanium Interference Screw ○ Ligament Staple ○ MENISCO Inside-Out Meniscal Repair Needle ○ MENI-FIX All-Inside Meniscal Repair System ○ AUXILOCK BioBraid 	<p>IIb</p>

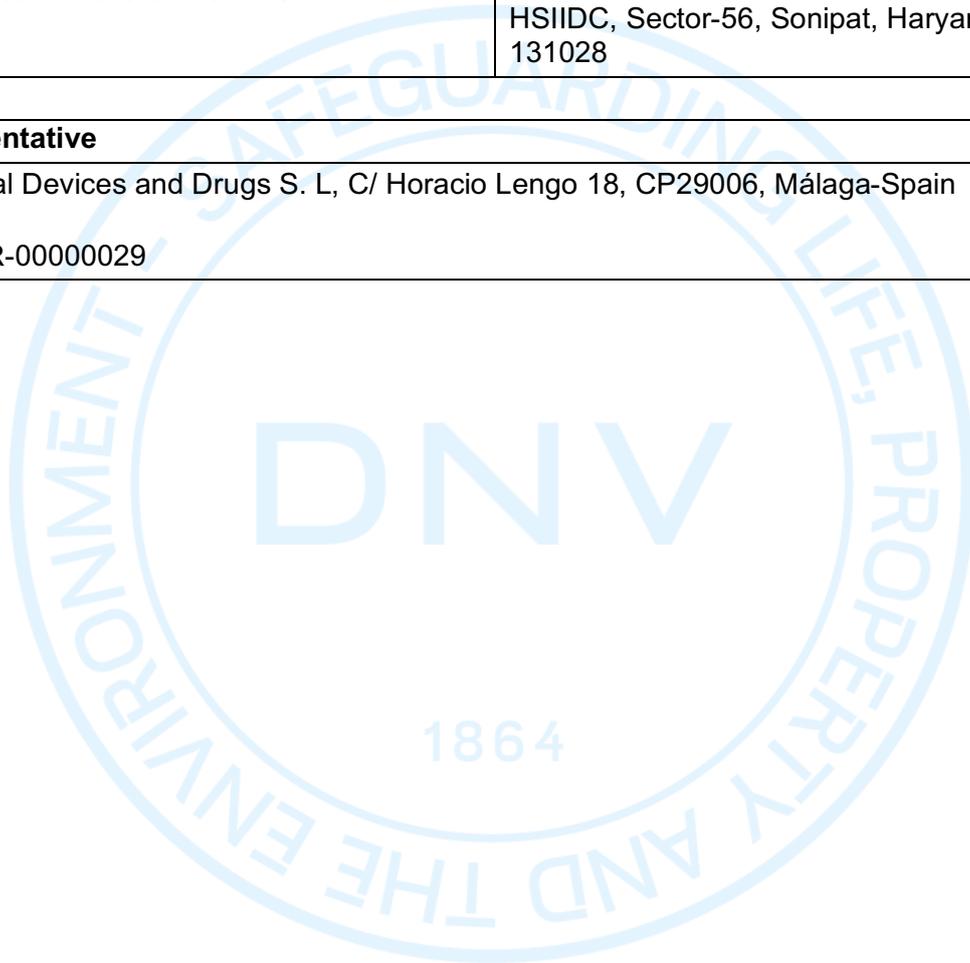
* Class III and class IIb devices referred to in the second subparagraph of Article 52(4): Technical documentation assessment is covered by a separate EU Technical Documentation Assessment Certificate No.: C642947, **C828958**

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Auxein Medical Private Limited – Unit I	Plot No. 168-169-170, Phase-4, Kundli Industrial Area, HSIIDC, Sector-57, Sonapat - 131028, Haryana, India
Auxein Medical Private Limited – Unit II	Plot No. 157, Phase-V, Kundli Industrial Area, HSIIDC, Sector-56, Sonipat, Haryana, India, 131028

EU Representative
CMC Medical Devices and Drugs S. L, C/ Horacio Lengo 18, CP29006, Málaga-Spain SRN: ES-AR-00000029



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 the Notified Body of any intended updating of the quality system and the Notified Body 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. Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.
- For the class III devices and IIb devices falling under Article 52 (4) covered this certificate is dependent on the continued validity of the EU Technical Documentation Assessment Certificate, covering the devices.

The following may render this Certificate invalid:

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

Specific conditions - Class I devices, Systems and Procedure Packs:

- For class I device being placed on the market in a sterile condition, Class I devices with a measurement function and class I devices being reusable surgical instruments covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 52(7) of the regulation.
- For system and procedure packs being placed on the market in a sterile condition, covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 22(3) of the regulation.
- For Custom Made Class III implantable device the certification only relates to the Quality management system. Technical documentation assessment and issuance of EU Technical Documentation Assessment Certificate does not apply.

Conformity declaration and marking of product

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