

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, 17 August 2026



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

Bhautik Khanpara
Management Representative

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
3.0	Addition of Components of Elastic Nailing System, Components of Tibia Nailing System, Components of Femur Plate System, Components of Clavicle and Scapula Plate System, Components of Hand Plate System, Components of Cervical Plate System, Components of Pediatric System, Components of Humerus Nailing System, Components of Ankle Plate System, Components of Pelvic Plate System, Components of CMF Plate System. Added the intended purpose for Components of Knee arthroscopy system, Product description updated	3566823	17 August 2026

Products covered by this Certificate:

Product Description (and intended purpose for class IIb)	Product Name	Class*
Components of Femur Nailing System (Sterile/Non-Sterile) Components of Femur Nailing System is intended to stabilize Femoral shaft fractures, Trochanteric Fractures, Ipsilateral Neck and Femoral Head, Impending Pathologic Fractures, Nonunions and Malunions of femur bone.	1. AJAX Advance Nail, Short and Long (Left/Right), Titanium with - 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 2. Expert Femur Nail, Left/Right, Stainless Steel/Titanium with - End Caps for Expert Femur Nail, Stainless Steel/Titanium - Ø4.8mm Locking Bolt, Self-Tapping, For Expert Femur Nail, Stainless Steel/Titanium	IIb

	• Ø6.4mm Cannulated Anti-Rotation Screw, Self-Tapping, For Expert Femur Nail, Stainless Steel/Titanium 3. Retrograde Femur Nail, Stainless Steel/Titanium with • 5.0mm Locking Screw for Retrograde Femur Nail, Stainless Steel/Titanium • End Cap for Retrograde Femur Nail, Stainless Steel/Titanium 4. ATHOS Nail, Stainless Steel/Titanium following Variants • 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 With following accessories • 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 • Ø6.4mm Cannulated Anti-Rotation Screw for Athos Nail, Stainless Steel/Titanium • Ø10.5mm Cephalic Screw, For Athos Nail, Stainless Steel/Titanium 5. JIN-Type Femur Nail, Stainless Steel/Titanium with • End Cap for JIN Type – Femur Nail, Stainless Steel/Titanium • Ø4.5mm Locking Bolt, Self-Tapping, For JIN Type – Femur Nail, Stainless Steel/Titanium 6. KONZEPT Femur Nail also known as Universal Intramedullary Cannulated Femur Nail, Left/Right, Stainless Steel/Titanium with • 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	
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	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	
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Components of Tibia Plate System (Sterile/Non-Sterile) Components of Tibia Plate System are intended to treat Non-union, Malunions and fracture of tibia bone.	Tibia Plates: (Stainless steel and Titanium), Left/Right • 3.5mm AV-Wiselock Proximal Tibia Plate, Small Bend • 3.5mm AV-Wiselock Proximal Tibia Plate, Large Bend • 3.5mm AV-Wiselock Medial Proximal Tibia Plate • 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 Tibia Plate (LISS) • 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 Bone Screws: (Stainless steel and Titanium) • 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)	IIb
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	• 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) • 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	
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Components of Foot Plate System (Sterile/Non-Sterile) Components of Foot Plate System are intended to treat Non- union, Malunions and fracture of foot bone.	Foot Plate System: (Stainless steel and Titanium), Left/Right • Ø2.7mm-6.0mm Metatarsal Shortening Implant • 2.4mm AV-Wiselock Endosteal Plate, Standard, Left/Right, Titanium • 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, Left/Right, Stainless Steel/Titanium • 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 Steel/Titanium • 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	IIb
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	• 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 Steel/Titanium • 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 Tapping, (Hex Head), Stainless Steel/Titanium • 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	
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	• 3.5mm Headless Cannulated Screw, Mini, Titanium • 4.0mm Headless Cannulated Screw, Standard, Titanium • 4.7mm Headless Cannulated Screw, Titanium • 5.5mm Headless Cannulated Screw, Titanium • 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	
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Components of Radius Plate System (Sterile/Non-Sterile) Components of Radius Plate System are intended to treat Non- union, Malunions and fracture of Radius bone.	Radius Plate System: (Stainless steel and Titanium), Left/Right • 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 • 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 Shaft Holes: 7 • 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	IIb
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	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 Dorsal Plate, Straight, Titanium Shaft Holes: 5, 6 • 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 Volar Plate, Extra-Long, Left/Right, Titanium	
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	Shaft Holes: 8, 10, 12 Head Holes: 4 • 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 Head), Length 12mm, Stainless Steel/Titanium Length (mm): 12 to 24 • 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	
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Components of Humerus Plate System (Sterile/Non-Sterile) Components of Humerus Plate System are intended to treat Non- union, Malunions and fracture of Humerus bone.	Humerus Plate System: (Stainless steel and Titanium), Left/Right • 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 Angled, Titanium/Stainless Steel • 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 • 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	lib
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	• 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 • 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 Head) • 3.5mm Cancellous Screw, Short Thread • 3.5mm Cancellous Screw, Full Thread	
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Place and date: Høvik, 17 August 2026

Components of Shoulder Arthroscopy System (sterile) 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	• 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 • 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	IIb
Components of Knee Arthroscopy System (sterile) Components of Knee Arthroscopy System are indicated to be used in the surgical procedures related to the Knee Ligament/Tendon and meniscus fixation.	• 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	IIb
Components of Elastic Nailing System (Sterile/Non-Sterile) Components of Elastic Nailing System are intended to maintain anatomical integrity of the fracture site by temporary fixation and stabilization of bone fragments.	• Elastic Nail • End Cap for Elastic Nail, Size 1 • End Cap for Elastic Nail, Size 2	IIb
Components of Tibia Nailing System (Sterile/Non-Sterile) Components of Tibia Nailing	• Expert Tibia Nail • End Cap for Expert Tibia Nail • Ø4.4mm Locking Bolt, Self-Tapping, For Expert Tibia Nail • Ø4.8mm Locking Bolt, Self-Tapping, For Expert	IIb

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System are intended to maintain anatomical integrity of the fracture site by temporary fixation and stabilization of tibia bone fragments.	- Tibia Nail - JIN Type - Tibia Nail - End Cap For JIN Type -Tibia Nail - Ø4.5mm Locking Bolt, Self-Tapping, For JIN Type - Tibia Nail - Interlocking Cannulated Tibia Nail (Konzept Tibia Nail) - End Cap For Interlocking Cannulated Tibia Nail - Compression Screw For Interlocking Cannulated Tibia Nail - Ø4.5mm Locking Bolt For Interlocking Cannulated Tibia Nail	
Components of Femur Plate System (Sterile/Non-Sterile) Components of Femur Plate System are intended to maintain anatomical integrity of the fracture site by temporary fixation and stabilization of femur bone fragments.	4.5/5.0mm AV-Wiselock Condylar Femur Plate 4.5/5.0mm AV-Wiselock Distal Femur Plate 5.0mm Wise-Lock Cable Prosthesis and Revision Femur Plate 5.0mm Wise-Lock Cable Straight Plate 4.5/5.0mm Wise-Lock Distal Femur Plate 4.5/5.0mm Wise-Lock Condylar Femur Plate 4.5/5.0mm Wise-Lock Proximal Femur Plate 4.5/5.0mm Wise-Lock Proximal Femur Hook Plate 4.5/5.0mm Wise-Lock Proximal Femur Lateral Plate (Type-II) 4.5/5.0mm Wise-Lock Narrow Dynamic Compression Plate with LC under cuts 4.5/5.0mm Wise-Lock Broad Dynamic Compression Plate with LC under cuts 4.5/5.0mm Wise-Lock Curved Broad Plate 4.5/5.0mm Wise-Lock Osteotomy Lateral Distal Femur Plate 4.5/5.0mm Wise-Lock Osteotomy Medial Distal Femur Plate 5.0mm Wise-Lock Distal Femur Plate (LISS) 5.0mm Wise-Lock Femoral Neck Plate - Wise-Lock DHS Plate - Wise-Lock DHS Plate, Short Barrel 95° Wise-Lock DCS Plate 4.5/5.0mm Wise-Lock Trochanter Stabilizing Plate for DHS – Adjustable - Dynamic Hip Compression Plate 135° Dynamic Hip Compression Plate, Short Barrel 95° DCS Plate 95° Condylar Blade Plate 130° Angle Blade Plate - Angle Blade Plate for Adults - Angle Blade Plate for Intertrochanteric - Femoral Osteotomies in Adults 4.5mm Narrow Dynamic Compression Plate 4.5mm Narrow Limited Contact Dynamic Compression Plate 4.5mm Broad Dynamic Compression Plate 4.5mm Broad Limited Contact Dynamic Compression Plate 4.5mm Narrow Lengthening Plate 4.5mm Broad Lengthening Plate 4.5mm Condylar Buttress Plate	IIb

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	• 4.5mm Cobra Head Plate • 4.5mm Proximal Femur Plate • 4.5mm Distal Femur Plate • 130°/135° Jewett Nail Plate • DHS/DCS Compression Screw • DHS/DCS Screw • Cable • Cable Connector, Curve Bone • Bone Needle • Bone Needle with Hole • Ø10.0mm Bolt for Femoral Neck Plate, Length 75mm, Titanium • 4.5mm Cortical Screw, Self-Tapping, (Hex Head) • 5.0mm Wise-Lock Screw, Self-Tapping, (Hex Head) • 6.5mm Cancellous Screw, 16mm Thread • 6.5mm Cancellous Screw, 32mm Thread • 6.5mm Cancellous Screw, Full Thread • 6.5mm Cannulated Screw, 16mm Thread, Self-Drilling • 6.5mm Cannulated Screw, 32mm Thread, Self-Drilling • 6.5mm Cannulated Screw, Full Thread, Self-Drilling • 7.0mm Cannulated Cancellous Screw, 16mm Thread, Self-Drilling • 7.0mm Cannulated Cancellous Screw, 32mm Thread, Self-Drilling • 7.0mm Cannulated Cancellous Screw, Full Thread, Self-Drilling • 7.3mm Cannulated Cancellous Screw, 16mm Thread, Self-Drilling • 7.3mm Cannulated Cancellous Screw, 32mm Thread, Self-Drilling • 7.3mm Cannulated Cancellous Screw, Full Thread, Self-Drilling • Ø6.4mm Anti-Rotation Screw for Femoral Neck Plate, Length 75mm • 5.0mm AV-Wiselock Screw, Self-Tapping, (Star Head) • 4.5mm Cortical Screw, Self-Tapping, (Star 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 • Washer For Large Fragment Screw	
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Components of Clavicle and Scapula Plate System (Sterile/Non-Sterile) Components of Clavicle and Scapula Plate System are intended to maintain anatomical integrity of the fracture site by temporary fixation and stabilization of clavicle and scapula bone fragments.	• 3.5mm Wise-Lock Reconstruction Plate • 3.5mm Wise-Lock Symphyseal Plate with Coaxial Combi-Holes • 3.5mm Wise-Lock Clavicle Hook Plate • 3.5mm Wise-Lock Superior Anterior Clavicle Plate • 3.5mm Wise-Lock S Clavicle Plate • 3.5mm Clavicle Hook Plate • 3.5mm Wise-Lock Scapula Glenoid Plate • 3.5mm Wise-Lock Scapula Acromion Plate • 3.5mm Wise-Lock Scapula Lateral Border Plate • 3.5mm Wise-Lock Scapula Medial Border Plate • 2.7/3.5mm Wise-Lock Superior Anterior Clavicle Plate with Lateral Extension • 2.7/3.5mm AV-Wiselock Superior Anterior Clavicle Plate with Lateral Extension • 3.5mm Wise-Lock Low Profile Reconstruction Plate with Coaxial Combi-Holes • 3.5mm Wise-Lock "J" Reconstruction Plate with Coaxial Combi-Holes • 2.7mm Wise-Lock Screw, Self-Tapping (Hex Head) • 3.5mm Cortical Screw, (Hex Head) • 3.5mm AV-Wiselock Screw, Self-Tapping • 3.5mm Wise-Lock Screw, Self-Tapping, (Star Head) • 3.5mm Cortical Screw, Self-Tapping, (Star Head) • 3.5mm Cortical Screw, Self-Tapping, (Hex Head) • 3.5mm Wise-Lock Screw, Self-Tapping (Hex Head)	IIb
Components of Hand Plate System (Sterile/Non-Sterile) Components of Hand Plate System are intended to maintain anatomical integrity of the fracture site by temporary fixation and stabilization of phalanges, metacarpals, carpals, wrist bone, Distal Radius bone fragments.	• 2.4mm AV-Wiselock RSL Fusion M Plate • 2.4mm AV-Wiselock Wrist Fusion M Plate • 2.4mm AV-Wiselock Dorsal Wrist Fusion M Plate, Radiocapitate • 2.4mm AV-Wiselock Dorsal Total Wrist Fusion M Plate • 1.5mm Wise-Lock Plate, Straight • 1.5mm Wise-Lock Adaption Plate, Straight • 1.5mm Wise-Lock Adaption T-Plate • 1.5mm Wise-Lock Strut Plate • 1.5mm Wise-Lock Adaption Y-Plate • 1.5mm Wise-Lock Condylar Plate • 2.0mm Wise-Lock Plate, Straight • 2.0mm Adaption Plate • 2.0mm Wise-Lock Adaption Plate, Straight • 2.0mm Wise-Lock Condylar Plate • 2.0mm Wise-Lock Rotation Correction Plate • 2.0mm Wise-Lock T-Plate • 2.0mm Wise-Lock T-Adaption Plate • 2.0mm Wise-Lock Y-Adaption Plate • 2.0mm Mini Condylar Plate • 2.0mm Wise-Lock Mini H-Plate • 2.0mm Wise-Lock Distal Ulna Hook Plate • 2.4mm Wise-Lock Plate, Straight • 2.4mm Adaption Plate, Straight • 2.4mm Wise-Lock Adaption Plate, Straight • 2.4mm Wise-Lock Condylar Plate • 2.4mm Wise-Lock T-Adaption Plate • 2.4mm Wise-Lock T-Plate	IIb

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	• 2.4mm Wise-Lock Y-Adaption Plate • 3.5mm Wise-Lock Wrist Fusion Plate (Standard bend, Short bend & Straight Bend) • 0.8mm Wise-Lock Low Profile Avulsion Fracture Plate • 0.8mm Wise-Lock Low Profile Straight Plate • 0.8mm Wise-Lock Low Profile Curved Medial/Lateral Plate • 0.8mm Wise-Lock Low Profile Curved Medial/Lateral Plate, Short • 0.8mm Wise-Lock Low Profile Compression Plate • 0.8mm Wise-Lock Low Profile T-Plate • 0.8mm Wise-Lock Low Profile L-Plate • 0.8mm Wise-Lock Low Profile Offset Plate • 1.3mm Wise-Lock Low Profile Metacarpal Neck Plate • 1.3mm Wise-Lock Low Profile Compression Plate • 1.3mm Wise-Lock Low Profile Straight Plate • 1.3mm Wise-Lock Low Profile T-Plate • 1.3mm Wise-Lock Low Profile Rolando Fracture Hook Plate • 1.3mm Wise-Lock Low Profile Rotational Correction Plate • 2.0mm Mini "L" Plate – Left/Right • 2.0mm Mini Straight Plate • 2.0mm DCP Plate • 2.0mm Mini "T" Plate • Staple U - Type • Straight Staple • Staple with Offset • Three-Legged Staple • Staple Coventry • Steinmann Pins • Centrally Threaded Steinmann Pin • Suture Wire • Kirschner Wire with Trocar Tip Both End • Kirschner Wire Fully Threaded • Circlage Wire with Loop • Kirschner Wire with One Side Trocar Tip • 1.5mm Cortical Screw, Self-Tapping, (Star Head) • 1.5mm Wise-Lock Screw, Self-Tapping, (Star Head) • 1.8mm Buttress Screw, (Star Head) • 2.0mm Cortical Screw, Self-Tapping, (Star Head) • 2.0mm Wise-Lock Screw, Self-Tapping, (Star Head) • 2.4mm Cortical Screw, Self-Tapping, (Star Head) • 2.4mm Variable Angle Screw, Self-Tapping, (Star Head) • 2.4mm Wise-Lock Screw, Self-Tapping, (Star Head) • 1.5mm Wise-Lock Low Profile Screw, (Star Head) • 1.5mm Low Profile Screw, (Star Head) • 2.3mm Wise-Lock Low Profile Screw, (Star Head) • 2.3mm Low Profile Screw • 1.5mm Cortical Screw, (Hex Head)	
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	• 1.5mm Cortical Screw, Self-Tapping, (Hex Head) • 2.0mm Cortical Screw, (Hex Head) • 2.0mm Cortical Screw, Self-Tapping, (Hex Head) • 2.7mm Cortical Screw, (Hex Head) • 2.7mm Cortical Screw, Self-Tapping, (Hex Head) • 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 Cortical Screw, Self-Tapping, (Hex Head)	
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Components of Cervical Plate System (Sterile/Non-Sterile) Components of Cervical Plate System are intended for anterior inter-body screw fixation of the cervical spine during the development of a cervical spinal fusion.	• Asterius-3.5mm Cancellous Screw, Self-Tapping, (Cross Head), Titanium • Asterius-4.0mm Cancellous Screw, Self-Tapping, (Cross Head), Titanium • Asterius-3.5mm Cancellous Screw, Self-Drilling, (Cross Head), Titanium • Asterius-4.0mm Cancellous Screw, Self-Drilling, (Cross Head), Titanium • Asterius-3.5mm Cancellous Screw, Self-Tapping, (Hex Head), Titanium • Asterius-4.0mm Cancellous Screw, Self-Tapping, (Hex Head), Titanium • Asterius-3.5mm Cancellous Screw, Self-Drilling, (Hex Head), Titanium • Asterius-4.0mm Cancellous Screw, Self-Drilling, (Hex Head), Titanium • REGEX-Anterior Cervical Plate, Level-I, Titanium • REGEX-Anterior Cervical Plate, Level-II, Titanium • REGEX-Anterior Cervical Plate, Level-III, Titanium • REGEX-Anterior Cervical Plate, Level-IV, Titanium • 4.0mm REGEX-Bone Screw, Self-Drilling, Variable Angled, Titanium • 4.0mm REGEX-Bone Screw, Self-Drilling, Fixed Angled, Titanium • 4.5mm REGEX-Bone Screw, Self-Drilling, Variable Angled, Titanium • 4.5mm REGEX-Bone Screw, Self-Drilling, Fixed Angled, Titanium • 4.0mm REGEX-Bone Screw, Self-Tapping, Variable Angled, Titanium • 4.0mm REGEX-Bone Screw, Self-Tapping, Fixed Angled, Titanium • 4.5mm REGEX-Bone Screw, Self-Tapping, Variable Angled, Titanium • 4.5mm REGEX-Bone Screw, Self-Tapping, Fixed Angled, Titanium • Asterius-Anterior cervical Plate	IIb
Components of Pediatric System (Sterile/Non-Sterile) Components of Pediatric System are indicated for fixation of fractures (including pathologic and impending pathologic fractures) and osteotomies of the femur, distal femur and proximal tibia in children	• Epiphyseal Plate, Terrace Shape • Epiphyseal Plate, Arc-Bridge Shape • 3.5mm Wise-Lock Pediatric Hip Plate • 4.5/5.0mm Wise-Lock Pediatric Hip Plate • 3.5mm Wise-Lock Pediatric Hip Plate (Type-II) • 5.0mm Wise-Lock Pediatric Hip Plate (Type-II) • 4.5mm Cortex Screw, Self-Tapping, Cannulated, (3.0mm Hex) • 3.5mm Wise-Lock Screw, Self-Tapping, (Hex Head) • 3.5mm Cortical Screw, Self-Tapping, (Hex Head) • 4.5mm Cortical Screws, Self-Tapping, (Hex Head) • 5.0mm Wise-Lock Screw, Self-Tapping, (Hex Head)	IIb
Components of Humerus Nailing System (Sterile/Non-Sterile) Components of Humerus	• Intramedullary Cannulated Humerus Nail • End Cap for Intramedullary Humerus Nail • Compression Screw for Intramedullary Humerus Nail • Ø4.5mm Locking Bolt for Humerus Nail • Ø4.5mm Proximal Screw	IIb

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Nailing System are intended to maintain anatomical integrity of the fracture site by temporary fixation and stabilization of humerus bone fragments.	• Reconstruction Nail, Cannulated • Reconstruction Cannulated Intramedullary Humerus Nail • End Cap for Reconstruction Cannulated Intramedullary Nail • Ø3.5mm Locking Bolt for Humerus Nail • JIN Type - Humerus Nail • End Cap For JIN Type -Humerus Nail • Ø3.5mm Locking Bolt, Self-Tapping, For JIN Type - Humerus Nail	
Components of Ankle Plate System (Sterile/Non-Sterile) Components of Ankle Plate System are intended to maintain the anatomical integrity of ankle bones through fixation, correction, and stabilization of bones in the ankle region promoting proper bone alignment and healing.	• 2.7/3.5mm AV-Wiselock Medial Distal Tibia Plate • 2.7/3.5mm AV-Wiselock Anteromedial Distal Tibia Plate • 2.7mm AV-Wiselock Lateral Distal Fibula Plate • 2.7mm AV-Wiselock Distal Tibia L-Plate • 2.7mm AV-Wiselock Distal Tibia T-Plate • 2.7/3.5mm AV-Wiselock Anterolateral Distal Tibia Plate • 4.5/5.0mm AV-Wiselock Anterior Tibiotalar Fusion Plate • 3.5mm Wise-Lock Lateral Distal Fibula Plate • 3.5mm Wise-Lock Z-Type Distal Lateral Fibular Plate • 3.5mm Wise-Lock One Third Tubular Plate • Distal Fibular Plate • 4.5mm Semi Tubular Plate • 3.5mm One Third Tubular Plate • 3.5mm Semi Tubular Plate • 3.5mm One-Third Tubular Plate with Collar • 2.7mm AV-Wiselock Screw, Self-Tapping, (Star Head) • 2.7mm Cortical Screw, Self-Tapping, (Star Head) • 2.7mm Wise-Lock Screw, Self-Tapping, (Star Head) • 3.5mm AV-Wiselock Screw, Self-Tapping, (Star Head) • 3.5mm Wise-Lock Screw, Self-Tapping, (Star Head) • 3.5mm Cortical Screw, Self-Tapping, (Star Head) • 3.5mm Cortical Screw, Self-tapping (Hex Head) • 3.5mm Wise-lock Screw, Self-tapping (Hex Head) • 4.0mm Cancellous Screw, Short Thread • 4.0mm Cancellous Screw, Full Thread • 4.5mm Cortical Screw, Self-tapping (Hex Head) • 4.5mm AV-Wiselock Low Profile Cortical Screw, Self-Tapping, (Star Head) • 4.5mm Cortical Screw, Self-Tapping, (Star Head) • 4.5mm Cannulated Cortical Screw, Short Thread • 4.5mm Cannulated Cortical Screw, Full Thread • 5.5mm Low Profile Cancellous Screw, Self-Tapping, (Star Head)	IIb
Components of Pelvic Plate System (Sterile/Non-Sterile) Components of Pelvic Plate System are intended to provide fixation of fractures,	• 3.5mm Pubic Symphysis Plate • 3.5mm Posterior Wall Acetabular Fragment Plate • 3.5mm Curved Posterior Wall Acetabular Fragment Plate • 3.5mm Superior Sacro-iliac Plate	IIb

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fusions, and osteotomies of the acetabulum, sacrum, ilium, and entire pelvic ring, as well as treatment of sacroiliac joint.	• 3.5mm Posterior Wall Acetabular Plate • 3.5mm Acetabular Spring Plate • 3.5mm Reconstruction Pelvis Plate • 3.5mm Interlocking Reconstruction Plate • 3.5mm Quadrilateral Surface Plate • 3.5mm Intrapelvic Plate, 05 Holes • 3.5mm Intrapelvic Plate, 09 Holes • 3.5mm Anterior Brim Plate, 12 Holes • 3.5mm Anterior Brim Plate, 14 Holes • 3.5mm Wise-Lock Low Profile Reconstruction Plate with Coaxial Combi-Holes, Curved • 3.5mm Wise-Lock Reconstruction Plate, Curved • 3.5mm Pelvic Reconstruction Plate, Straight • 3.5mm Pelvic Reconstruction Plate, Curved • 3.5mm Low Profile Cortical Screw, (Hex Head) • 4.0mm Low Profile Cancellous screw, (Hex Head) • 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 Cortical Screw, Self-Tapping, (Hex Head) • 3.5mm Cortical Screw, (Hex Head)	
Components of CMF Plate System (Sterile/Non-Sterile) Components of CMF Plate System are intended to treat the fracture of Cranial/Midface bone.	• 1.0mm Straight Plate • 1.0mm L-Plate, 90° • 1.0mm Double Y Plate • 1.0mm Y-Plate with Bridge • 1.0mm Y-Plate • 1.0mm T-Plate • 1.0mm Square Plate • 1.0mm Rectangular Grill Plate, Type-I • 1.0mm Rectangular Grill Plate, Type-II • 1.0mm Rectangular Grill Plate, Type-III • 1.0mm Orbital Floor Plate, Type-I • 1.0mm Orbital Floor Plate, Type-II • 1.0mm Orbital Floor Plate, Type-III • 1.0mm Orbital Floor Plate, Type-IV • 1.0mm Orbital Floor Plate, Type-V • 1.0mm Orbital Floor Plate, Type-VI • 1.0mm Orbital Floor Plate, Type-VII • 1.0mm Orbital Floor Plate, Type-VIII • 1.5mm Straight Plate • 1.5mm Plate • 1.5mm Continuous Plate • 1.5mm Orbital Plate • 1.5mm Continuous Orbital Plate • 1.5mm L-Plate • 1.5mm L-Plate with Bridge • 1.5mm Double X-Plate, Small • 1.5mm Double X-Plate, Medium • 1.5mm Double X-Plate, Large • 1.5mm X-Plate • 1.5mm Double X-Plate with Support • 1.5mm Cross Bend Plate • 1.5mm Y-Plate with Bridge, Type-I • 1.5mm Y-Plate with Bridge, Type-II • 1.5mm Y-Plate • 1.5mm H-Plate	IIb

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	• 1.5mm H-Plate, Big • 1.5mm H-Plate, Curve • 1.5mm I-Plate • 1.5mm T-Plate • 1.5mm T-Plate with Bridge • 1.5mm T-Plate, Long • 1.5mm T-Plate, Long-Oblique • 1.5mm Z-Plate • 1.5mm T-Plate, Oblique • 1.5mm Square Plate • 1.5mm Rectangular Grill Plate, Type-I • 1.5mm Rectangular Grill Plate, Type-II • 1.5mm Triangular Plate • 1.5mm Rectangular Grill Plate, Type-III • 1.5mm Rectangular Grill Plate, Type-IV • 1.5mm Rectangular Grill Plate, Type-V • 1.5mm T-Gap Plate, Angled • 1.5mm T-Gap Plate, Straight • 1.5mm Orbital Floor Plate, Type-III • 1.5mm Orbital Floor Plate, Type-VIII • 1.5mm Orbital Floor Plate, Type-IV • 1.5mm Orbital Floor Plate, Type-VII • 1.5mm Orbital Floor Plate, Type-VI • 1.5mm Maxilla Plate, Space • 1.5mm Chin Plate • 2.0mm Straight Plate • 2.0mm Straight Plate with Bridge, Type-I • 2.0mm Straight Plate 2 Holes, Type-I • 2.0mm Straight Plate with Bridge, Type-II • 2.0mm Straight Plate 5 Holes, Type-I • 2.0mm Straight Plate 6 Holes, Type-I • 2.0mm L-Plate with bridge, Type-I, 90° • 2.0mm L-Plate, Type-I, 90° • 2.0mm L-Plate with Bridge, Type-II, 90° • 2.0mm L-Oblique Plate with Bridge, 90° • 2.0mm Straight Plate with Bridge, Type-III • 2.0mm Straight Plate, Type-II • 2.0mm Straight Plate with Bridge, Type IV • 2.0mm Orbital Plate with Bridge, Type-I • 2.0mm Orbital Plate with Bridge, Type-II • 2.0mm Orbital Plate • 2.0mm L-Plate, Type-II, 90° • 2.0mm L-Plate with Bridge, Type-III, 90° • 2.0mm L-Plate with Bridge, 100° • 2.0mm L-Plate, 130° • 2.0mm L-Plate with Bridge, Type-IV, 90° • 2.0mm Double X-Plate, Small • 2.0mm H-Plate • 2.0mm Long T-Plate, Oblique Angle • 2.0mm I-Plate • 2.0mm T-Plate with Bridge • 2.0mm T-Plate • 2.0mm Z-Plate • 2.0mm Pseudo-Possessed Plate, Type-III • 2.0mm Rectangular Grill Plate, Type-II • 2.0mm Rectangular Grill Plate, Type-I	
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Certificate no.: C721730
Place and date: Høvik, 17 August 2026

	• 2.0mm Rectangular Grill Plate, Type -III • 2.0mm Rectangular Grill Plate, Type -IV • 2.0mm Locking Straight Plate with Bridge, Type-I • 2.0mm Locking T-Gap Plate, Straight • 2.0mm Locking U-Plate • 2.0mm Locking Square Frame Plate, Type-I • 2.0mm Locking Rectangular Grill Plate, Type-I • 2.0mm Locking Rectangular Grill Plate, Type-II • 2.0mm Locking Straight Plate with Bridge, Type-II • 2.0mm Locking Rectangular Grill Plate, Type-III • 2.0mm Locking Straight Plate with Bridge, Type-III • 2.0mm Locking Straight Plate, Type-II • 2.0mm Locking Straight Plate with Bridge, Type-IV • 2.0mm Locking Straight Plate with Bridge, Type-V • 2.0mm Locking Straight Plate, Type-III • 2.0mm Locking Curved Plate, Type-I • 2.0mm Locking Orbital Plate • 2.0mm One -Way Pressure Plate with Bridge • 2.0mm One -Way Pressure Plate • 2.0mm One -Way Pressure Curved Plate • 2.0mm One -Way Pressure Orbital Plate • 2.4mm Mandible Reconstruction Plate, Straight • 2.4mm Locking Two-way Compression Mandible Reconstruction Plate, Straight • 2.4mm Locking Round Holes Mandible Reconstruction Plate, Angled • 2.4mm Mandible Reconstruction Plate, Angled • 2.4mm Locking Two-Way Compression Mandible Reconstruction Plate, Angled • 2.4mm Locking Round Holes Mandible Reconstruction Plate, Straight • 2.4mm Mandible Reconstruction Plate, Double Angled • 2.4mm Locking Round Holes Mandible Reconstruction Plate, Double Angled • 2.4mm Locking Two-Way Compression Mandible Reconstruction Plate, Double Angled • 2.4mm Locking Two-Way Mandible Reconstruction Plate, Straight • 0.4mm Mini Plate • 0.6mm Mini Plate • 1.0mm Micro Plate • 0.6mm Low-incisura Plate • 0.8mm Micro Plate • 1.0mm Locking Plate • 1.2mm Locking Plate • 1.5mm One-Way Compression Plate • 2.0mm General Reconstruction Plate • 2.0mm Locking Reconstruction Plate • 2.0mm Two-Way Compression & Locking Reconstruction Plate • 2.5mm General Reconstruction Plate • 2.5mm Locking Reconstruction Plate • 2.5mm Two-Way Compression & Locking Reconstruction Plate • 1.0mm Self-Tapping Screw, Length 2 to 7mm	
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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
DMSH-5-MED-01-A4 v1 (Replaces MDR-CO-078-A V0.8)

	• 1.0mm Self-Tapping & Drilling Screw, Length 2 to 7mm • 1.3mm Emergency Screw, Self-Tapping, Length 2 to 7mm • 1.5mm Self-Tapping Screw, Length 3 to 15mm • 1.5mm Self-Tapping & Self Drilling Screw, Length 4 to 7mm • 1.9mm Emergency Screw, Self-Tapping, Length 3 to 15mm • 2.0mm Self-Tapping Screw, Length 4 to 19mm, Titanium • 2.0mm Self-Tapping & Self Drilling Screw, Length 4 to 19mm • 2.0mm Locking Self-Tapping Screw, Length 5 to 13mm • 2.0mm Locking Self-Tapping & Drilling Screw, Length 5 to 13mm • 2.3mm Emergency Screw, Self-Tapping, Length 5 to 19mm • 2.4mm Self-Tapping Screw, Length 7 to 19mm • 2.4mm Locking Self-Tapping Screw, Length 7 to 20mm • 2.7mm Emergency Screw, Self-Tapping, Length 7 to 20mm • 1.5mm Kirschner Screw, Length 18 to 24mm • 1.9mm Emergency Screw, Length 18 to 24mm • 2.0mm Kirschner Screw, Length 18 to 24mm • 2.3mm Emergency Screw, Length 18 to 24mm • 2.0mm Lag Screw, Length 18 to 24mm • 1.5mm Self-Tapping & Self Drilling IMF Screw, Type-I, Length 5 to 13mm • 1.5mm Self-Tapping & Self Drilling IMF Screw, Type-II, Length 5 to 13mm • 1.5mm Self-Tapping & Self Drilling IMF Screw, Type-III, Length 5 to 13mm • 2.0mm Self-Tapping & Self Drilling IMF Screw, Type-I, Length 5 to 13mm • 2.0mm Self-Tapping & Self Drilling IMF Screw, Type-II, Length 5 to 13mm • 2.0mm Self-Tapping & Self Drilling IMF Screw, Type-III, Length 5 to 13mm • 1.3mm Anchor Screw, Length 3.5 to 9.5mm	
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* 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.: Not Applicable

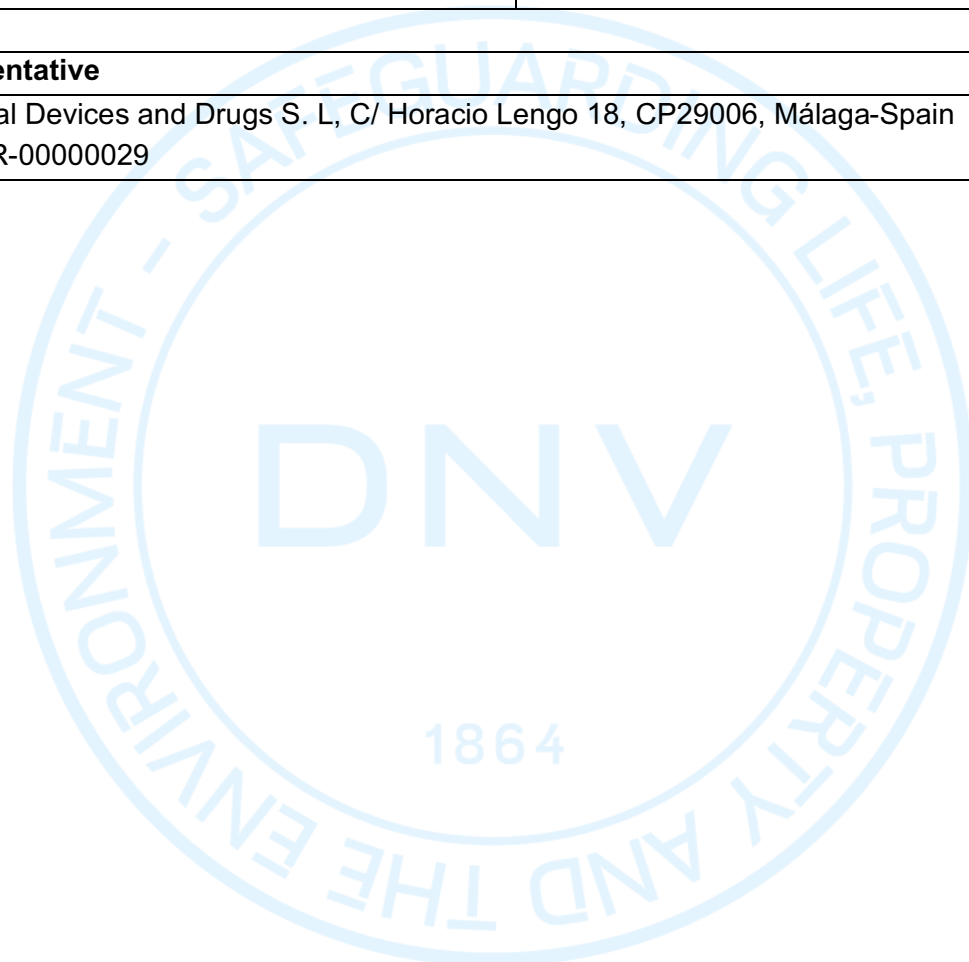
The complete list of devices is filed with the Notified Body

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.