



Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

EC Certificate - Full Quality Assurance System No. 18 0310 QS/NB

The quality system of manufacturer

Shagun Cares INC

**C-27, D.S.I.D.C Industrial Complex, Rohtak Road, Nangloi, New
Delhi 110041, India**

has been certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II excluding (4)

for the following product category(ies):

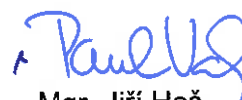
Orthopaedic Implants

The Notified Body No. 1023 declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subjected to periodical surveillance. For placing on the market of Class III devices covered by this certificate, an EC Design-Examination Certificate according to Annex II (Section 4) is required.

Valid from: 2018-09-11
Valid until: 2023-09-10
First Issued: 2018-09-11
Revision: -



Date: 2018-09-11


Mgr. Jiří Heš

Representative of the Notified Body No. 1023



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Annex to EC Certificate No. 18 0310 QS/NB

issued for manufacturer:

Shagun Cares INC

**C-27, D.S.I.D.C Industrial Complex, Rohtak Road, Nangloi, New
Delhi 110041, India**

Product(s):

Name: Orthopaedic bone screws
Trade name(s): Internal Fixation Systems, Ortho FIXOR, Shagun Cares
Model(s): see attached table
Class: IIb
GMDN: 56642

Name: Orthopaedic bone plates
Trade name(s): Internal Fixation Systems, Ortho FIXOR, Shagun Cares
Model(s): see attached table
Class: IIb
GMDN: 61573

Name: Maxillofacial implants
Trade name(s): Internal Fixation Systems, Ortho FIXOR, Shagun Cares
Model(s): see attached table
Class: IIb
GMDN: 46642



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Name:	Orthopaedic locking plates
Trade name(s):	Internal Fixation Systems, Ortho FIXOR, Shagun Cares
Model(s):	see attached table
Class:	IIb
GMDN:	61573
Name:	Orthopaedic wires and pins
Trade name(s):	Internal Fixation Systems, Ortho FIXOR, Shagun Cares
Model(s):	see attached table
Class:	IIb
GMDN:	61670 (wires), 35685 (pins)
Name:	Orthopaedic nails
Trade name(s):	Internal Fixation Systems, Ortho FIXOR, Shagun Cares
Model(s):	see attached table
Class:	IIb
GMDN:	33187, 47762



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Name:	Spinal implants
Trade name(s):	Internal Fixation Systems, Ortho FIXOR, Shagun Cares
Model(s):	see attached table
Class:	IIb
GMDN:	46651

Facility(ies):

Shagun Cares INC

C-27, D.S.I.D.C Industrial Complex, Rohtak Road, Nangloi, New Delhi 110041,
India (legal address and manufacturing site)

Shagun Cares INC

Sector B-3, Plot No. C 22, Tronica City Industrial Area, Ghaziabad 201102, Uttar
Pradesh, India (warehouse)



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Variants of the medical device covered by this certificate:

DEVICE NAME	DEVICE MODEL	GMDN CODE	MATERIAL
ORTHOPAEDIC BONE SCREWS			
1.5mm Cortical Screw	6mm to 20mm	56642	S.S/Ti
2.0mm cortical screws	6mm to 20mm	56642	S.S/Ti
2.7mm cortical screw	6mm to 30mm	56642	S.S/Ti
3.5mm cortical screw	10mm to 40mm	56642	S.S/Ti
3.5 mm Cancellous Screw	10 to 40 mm	56642	S.S/Ti
4.0 mm Cancellous screw (short thread)	10 to 60 mm	56642	S.S/Ti
4.0 mm Cancellous screw (Full thread)	10mm to 60 mm	56642	S.S/Ti
4.0 mm Cannulated screw (full thread)	10mm to 60 mm	56642	S.S/Ti
4.0 mm Cannulated screw (short thread)	10 mm to 60 mm	56642	S.S/Ti
4.5 Cortical screw	12mm to 120 mm	56642	S.S/Ti
4.5 mm Cortical screw (Self- Tapping)	12mm to 120 mm	56642	S.S/Ti
6.5 mm Cancellous screw (thread 16 mm)	12 mm to 100 mm	56642	S.S/Ti

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DEVICE NAME	DEVICE MODEL	GMDN CODE	MATERIAL
6.5 mm Cancellous screw (thread 32 mm)	35 mm to 100 mm	56642	S.S/Ti
6.5 mm Cancellous screw (Full thread)	25 mm to 100 mm	56642	S.S/Ti
7.0 mm & 6.5 mm Cannulated screw (16 thread)	50 mm to 110 mm	56642	S.S/Ti
7.0 mm & 6.5 mm Cannulated screw (32 thread)	50 mm to 110 mm	56642	S.S/Ti
7.0 mm & 6.5 mm Cannulated screw (Full thread)	50 mm to 110 mm	56642	S.S/Ti
4.5 mm Malleolar screw	25mm to 80 mm	56642	S.S/Ti
Compression screw	36 mm	56642	S.S/Ti
DHS/DCS Screw	50mm to 100 mm	56642	S.S/Ti
Herbert Screw	12mm to 40 mm	56642	S.S/Ti
4.9 mm Locking bolt Self tapping	24 mm to 95 mm	56642	S.S/Ti
3.9 mm Locking bolt Self tapping	20 mm to 60 mm	56642	S.S/Ti
Steffee Screw (4.5mm, 5.5mm, 6.5mm, 7.0mm)	28 mm to 44 mm	56642	S.S/Ti
Screw 1.0 mm	6 mm to 20 mm	56642	S.S/Ti

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DEVICE NAME	DEVICE MODEL	GMDN CODE	MATERIAL
Screw 1.3 mm	6 mm to 20 mm	56642	S.S/Ti
Screw 1.5 mm	6 mm to 20 mm	56642	S.S/Ti
Screw 2.0 mm	6 mm to 20 mm	56642	S.S/Ti
Screw 2.3 mm	6 mm to 20 mm	56642	S.S/Ti
Screw 2.5 mm	6 mm to 40 mm	56642	S.S/Ti
Screw 2.7 mm	6 mm to 40 mm	56642	S.S/Ti
Emergency screw	6 mm to 40 mm	56642	S.S/Ti
Locking thread Head screw 2.7 mm (self Tapping)	20 mm to 60 mm	56642	S.S/Ti
Locking thread Head screw 3.5 mm (self Tapping)	10 mm to 95 mm	56642	S.S/Ti
Locking thread Head screw 5.0 mm (self Tapping)	14 mm to 90 mm	56642	S.S/Ti
Locking thread Head screw 2.7 mm (self Drilling)	10 mm to 30 mm	56642	S.S/Ti
Locking thread Head screw 3.5 mm (self Drilling)	12 mm to 60 mm	56642	S.S/Ti
Locking thread Head screw 5.0 mm (self Drilling)	14 mm to 90 mm	56642	S.S/Ti
Locking thread Head screw 5.0 mm Cannulated	25 mm to 145 mm	56642	S.S/Ti

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DEVICE NAME	DEVICE MODEL	GMDN CODE	MATERIAL
Locking thread Head screw 2.0 mm (self Tapping)	10 mm to 30 mm	56642	S.S/Ti
Locking thread Head screw 2.4 mm (self Tapping)	10 mm to 30 mm	56642	S.S/Ti
Locking thread Head screw 2.0 mm (self Drilling)	10 mm to 30 mm	56642	S.S/Ti
Locking thread Head screw 2.4 mm (self Drilling)	10 mm to 30 mm	56642	S.S/Ti
Locking thread Head screw 6.5 mm (self Tapping)	30 mm to 120 mm	56642	S.S/Ti
Locking thread Head screw 7.0 mm (self Tapping)	30 mm to 120 mm	56642	S.S/Ti
Locking thread Head screw 7.3 mm (self Tapping)	30 mm to 120 mm	56642	S.S/Ti
Locking thread Head screw 7.3 Cannulated	30 mm to 120 mm	56642	S.S/Ti
Interference screw	30 mm to 120 mm	56642	S.S/Ti
ACL screw	30 mm to 120 mm	56642	S.S/Ti
ACL Pin	30 mm to 120 mm	56642	S.S/Ti

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DEVICE NAME	DEVICE MODEL	GMDN CODE	MATERIAL
4.5 mm Cortical cannulated screws Short thread	12mm to 42 mm	56642	S.S/Ti
4.5 mm Cortical cannulated screws full thread	12mm to 42 mm	56642	S.S/Ti
3.5mm cortical screw (Self tapping)	10mm to 50mm	56642	S.S/Ti
7.0 mm Cancellous cannulated screw (full thread)	12 mm to 100 mm	56642	S.S/Ti
Locking Bolt 6.5 mm	30 mm to 100 mm	56642	S.S/Ti
Locking bolt 7.5 mm	30 mm to 100 mm	56642	S.S/Ti
ORTHOPAEDIC BONE PLATES			
MINI STRAIGHT PLATE FOR 2.0 MM SCREW	2 holes to 8 holes	61573	S.S/Ti
MINI L- PLATE	Left & right	61573	S.S/Ti
DCP for 2.7mm screw	2 holes to 8 holes	61573	S.S/Ti
L – plate for 2.7 mm screw	Left & right	61573	S.S/Ti
T Plates For 2.7 mm screw	2 holes to 3 holes	61573	S.S/Ti
Straight Reconstruction Plate for 2.7 mm screws	5 holes to 24 holes	61573	S.S/Ti

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DEVICE NAME	DEVICE MODEL	GMDN CODE	MATERIAL
Quarter Tubular Plate for 2.7 mm screw	2 holes to 10 holes	61573	S.S/Ti
One – third tubular plate	2 holes to 12 holes	61573	S.S/Ti
Small T plate Oblique Angled	3 holes to 10 holes	61573	S.S/Ti
LC DCP 3.5 mm	3 holes to 12 holes	61573	S.S/Ti
Y Reconstruction Plate	3 holes to 10 holes	61573	S.S/Ti
DCP plate 3.5 mm	2 holes to 12 holes	61573	S.S/Ti
Straight Reconstruction Plate 3.5 mm	5 holes to 22 holes	61573	S.S/Ti
Small T plate right angle	3 holes to 10 holes	61573	S.S/Ti
Straight Reconstruction Plate 4.5 mm	5 holes to 18 holes	61573	S.S/Ti
Semi Tubular Plate for 4.5 mm screw	4 holes to 18 holes	61573	S.S/Ti
LC DCP 4.5 mm Broad	6 holes to 18 holes	61573	S.S/Ti

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DEVICE NAME	DEVICE MODEL	GMDN CODE	MATERIAL
DCP 4.5 mm Broad	6 holes to 20 holes	61573	S.S/Ti
DCP 4.5 mm Narrow	4 holes to 18 holes	61573	S.S/Ti
T Buttress Plate 4.5 mm	3 holes to 10 holes	61573	S.S/Ti
T plate 4.5 mm	3 holes to 10 holes	61573	S.S/Ti
Curved Reconstruction Plate 3.5 mm	3 holes to 18 holes	61573	S.S/Ti
Clover leaf Plate	3 holes to 10 holes	61573	S.S/Ti
Calcaneal Plate 3.5 mm	60 mm to 90 mm	61573	S.S/Ti
Narrow Lengthening Plate 4.5 mm	4 holes to 18 holes	61573	S.S/Ti
Spoon Plate	4 holes to 7 holes	61573	S.S/Ti
Cobra Head Plate	8 holes to 16 holes	61573	S.S/Ti
Hook Plate	6 holes to 7 holes	61573	S.S/Ti
Angled Blade Plate 90*	4 holes to 5 holes (60 mm length to 85 mm length)	61573	S.S/Ti

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DEVICE NAME	DEVICE MODEL	GMDN CODE	MATERIAL
Angle Blade Plate 120*	4 holes to 5 holes (60 mm length to 85 mm length)	61573	S.S/Ti
DHS Barrel Plate 120*	4 holes to 18 holes	61573	S.S/Ti
Steffee Plate	1 holes to 5 holes	61573	S.S/Ti
Condylar Plate 95* for Adults	5 holes to 14 holes Blade Length 50 to 80 mm	61573	S.S/Ti
Condylar Buttress Plate 4.5 mm	6 holes to 16 holes	61573	S.S/Ti
Lateral Tibia Head Buttress Plate 4.5 mm	6 holes to 16 holes	61573	S.S/Ti
L buttress Plate 4.5 mm Left & Right	3 holes to 14 holes	61573	S.S/Ti
Angled Blade Plate 130* For Adults	4 holes to 12 holes Blade Length 50 to 80mm	61573	S.S/Ti
DHS Plate 130*	4 holes to 16 holes	61573	S.S/Ti

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DEVICE NAME	DEVICE MODEL	GMDN CODE	MATERIAL
DHS Plate 135*	4 holes to 16 holes	61573	S.S/Ti
DCS Plate 95*	6 holes to 18 holes	61573	S.S/Ti
H plate for Cervical Spine	5 holes to 11 holes	61573	S.S/Ti
Semi tubular plate 3.5 mm	4 holes to 12 holes	61573	S.S/Ti
MAXILLOFACIAL IMPLANTS			
Three Dimensional Bone Plate Rectangular	-	46642	S.S/Ti
Mini Bone Plate Continuous Plate	4 holes to 24 holes	46642	S.S/Ti
Orbital plate continues plate	4 holes to 16 holes	46642	S.S/Ti
Reconstruction Plate for Mandibles	4 holes to 30 holes	46642	S.S/Ti
Splitfix Plate	-	46642	S.S/Ti
T plate with bar	-	46642	S.S/Ti
TMJ Condyle	-	46642	S.S/Ti
TMJ condyle With Reconstruction Angular Plate	-	46642	S.S/Ti

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DEVICE NAME	DEVICE MODEL	GMDN CODE	MATERIAL
Wire Meshes	-	46267, 46268	S.S/Ti
X Plate	-	46642	S.S/Ti
Y plate	-	46642	S.S/Ti
Z plate	-	46642	S.S/Ti
Nose Plate X shape	10 holes	46642	S.S/Ti
Maxilla Plate Left n Right 1.5 mm Dia	1.5 mm Dia	46642	S.S/Ti
Nose Plate	12 holes	46642	S.S/Ti
Mandible Plate	-	46642	S.S/Ti
Chine Plate	2.0 mm	46642	S.S/Ti
Chin Plate 2.0 Single Curved	-	46642	S.S/Ti
Chin Plate 2.0 Double Curved	-	46642	S.S/Ti
Mini straight plate for 2.0mm screw	2 holes to 8 holes	46642	S.S/Ti
Mini L plate	Left and Right	46642	S.S/Ti
Mini DCP 2.0 mm	4 holes to 8 holes	46642	S.S/Ti
Mini T Plate for 2.0mm screw	-	46642	S.S/Ti



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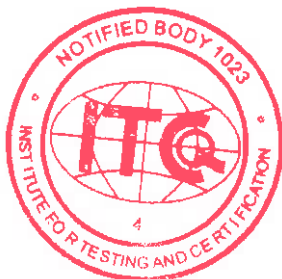
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DEVICE NAME	DEVICE MODEL	GMDN CODE	MATERIAL
ORTHOPAEDICS LOCKING PLATES			
1/3 Tubular Locking Plate	2 to 12 holes	61573	S.S/Ti
Small T Plate Right Angle Locking Plate	3 to 8 holes	61573	S.S/Ti
Small T Oblique Angled Locking Plate	3 to 8 holes	61573	S.S/Ti
3.5 Mm LCDCP Locking Plate	2 to 12 holes	61573	S.S/Ti
Mini T Locking Plate	2 to 8 holes	61573	S.S/Ti
Mini L Locking Plate Left And Right	3 to 8 holes	61573	S.S/Ti
Mini T Oblique Locking Plate Left & Right	2 to 12 holes	61573	S.S/Ti
Mini Straight Locking Plate	4 to 6 holes	61573	S.S/Ti
¼ Quarter Tubular Locking Plate	2 to 10 holes	61573	S.S/Ti
¼ Quarter Tubular Locking Plate For 2.7 mm Screw	4 to 6 holes	61573	S.S/Ti
Straight Reconstruction Plate For 2.7 mm Locking Screws	5 to 24 holes	61573	S.S/Ti
Straight Reconstruction Plate For 3.5 mm Locking Screws	5 to 22 holes	61573	S.S/Ti

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DEVICE NAME	DEVICE MODEL	GMDN CODE	MATERIAL
Straight Reconstruction Plate For 4.5 mm Locking Screws	4 to 16 holes	61573	S.S/Ti
Clover Leaf Locking Plate 3.5 mm	3 to 6 holes	61573	S.S/Ti
Clover Leaf Locking Plate 4.5 mm	3 to 12 holes	61573	S.S/Ti
4.5 mm Narrow LCDCP Locking Plate	4 to 22 holes	61573	S.S/Ti
4.5 mm Broad LCDCP Locking Plate	4 to 22 holes	61573	S.S/Ti
2.7 mm LCDCP Locking Plate	4 to 22 holes	61573	S.S/Ti
T Locking Plate 4.5 mm	3 to 12 holes	61573	S.S/Ti
L Buttress Locking Plate Left & Right	3 to 6 holes	61573	S.S/Ti
Proximal Lateral Tibia Locking Plate Left & Right	5 to 13 holes	61573	S.S/Ti
Distal Femur Locking Plate Left & Right	5 to 13 holes	61573	S.S/Ti
3.5 Semi Tubular Locking Plate	2 to 12 holes	61573	S.S/Ti



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DEVICE NAME	DEVICE MODEL	GMDN CODE	MATERIAL
5.0 mm Semi Tubular Locking Plate	4 to 14 holes	61573	S.S/Ti
Calcaneal Locking Plate 3.5 mm	64 mm to 81 mm	61573	S.S/Ti
Calcaneal Locking Plate 5.0 mm	64 mm to 81 mm	61573	S.S/Ti
DHS Locking Plate 120 To 150*	2 to 14 holes	61573	S.S/Ti
DCS Locking Plate 90*	4 to 22 holes	61573	S.S/Ti
Distal Humorous Locking Plate Without Support	3 to 14 holes	61573	S.S/Ti
Distal Humorous Locking Plate With Support	3 to 14 holes	61573	S.S/Ti
Oleaconon Locking Plate Left & Right	2 to 12 holes	61573	S.S/Ti
Distal Radius Locking Plate (assorted type & left-right)	3 to 12 holes	61573	S.S/Ti
Proximal Femur Locking Plate Left & Right	2 to 16 holes	61573	S.S/Ti
Proximal Femur Locking Hook Plate Left & Right	2 to 16 holes	61573	S.S/Ti

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Distal Tibia Locking Plate Left & Right	4 to 14 holes	61573	S.S/Ti
Proximal Humorous Locking Plate	3 to 12 holes	61573	S.S/Ti
Metaphyseal Plate 3.5 mm	6 to 18 holes	61573	S.S/Ti
Metaphyseal Plate 4.5 mm	3 to 15 holes	61573	S.S/Ti
Clavicle hook plate	4 to 7 holes (depth 12 mm to 18 mm)	61573	S.S/Ti
Philos Proximal humeral plate	5 to 12 holes	61573	S.S/Ti
Superior Anterior clavicle plate 3.5 mm	4 to 14 holes	61573	S.S/Ti
Superior Anterior clavicle plate 2.7/3.5 mm	3 to 8 holes	61573	S.S/Ti
Metaphyseal Distal Medial humorous 3.5 mm	4 to 20 holes	61573	S.S/Ti
Distal Medial Humeral	3 to 14 holes	61573	S.S/Ti
Pediatric Hip plate	Angles 100* to 150*	61573	S.S/Ti
Tomofix plate	3 to 4 holes (left- right)	61573	S.S/Ti

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Mgr. Jiří Heš
Representative of the Notified Body No. 1023



Notified Body 1023

INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 18 0310 QS/NB

issued for manufacturer:

Shagun Cares INC

**C-27, D.S.I.D.C Industrial Complex, Rohtak Road, Nangloi, New
Delhi 110041, India**

DEVICE NAME	DEVICE MODEL	GMDN CODE	MATERIAL
Proximal Tibia Plate 3.5 mm	4 to 16 holes	61573	S.S/Ti
Proximal Tibia Plate 5.0 mm	4 to 14 holes	61573	S.S/Ti
Medial Proximal Tibia 3.5 mm	4 to 20 holes	61573	S.S/Ti
Medial Proximal Tibia 5.0 mm	4 to 16 holes	61573	S.S/Ti
Distal tibia plate	4 to 14 holes	61573	S.S/Ti
Distal tibia Without Tab	4 to 14 holes	61573	S.S/Ti
Anterolateral distal tibia	5 to 21 holes	61573	S.S/Ti
Pilon plate	7 to 9 holes	61573	S.S/Ti
Two column Distal radius	2 to 13 holes	61573	S.S/Ti
Adaption plate	12 holes	61573	S.S/Ti
Condylar adaption plate	7 holes	61573	S.S/Ti
T adaption plate	7 holes	61573	S.S/Ti
Y adaption plate	7 holes	61573	S.S/Ti
ORTHOPAEDICS WIRES AND PINS			
Washer for 4.0 mm Cancellous screw	-	61670	S.S/Ti
Washer for 4.5 mm Malleolar screw and 6.5 mm Cancellous screw	-	61670	S.S/Ti

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DEVICE NAME	DEVICE MODEL	GMDN CODE	MATERIAL
Stainless Steel Wire	16 to 30 SWG	35685	S.S/Ti
Kirsehner wire With trocar Tip	Length 70 to 400 cm Dia 0.8 to 3.0 mm	35685	S.S/Ti
Hart shell	75 to 250 mm	35685	S.S/Ti
Drummer Wire	18 to 20 SWG	35685	S.S/Ti
Harrington Rod & hooks	Length 25 to 200 mm	61325	S.S/Ti
Stainmaan Pin	Length 150 to 300mm Dia 3.0 to 5.0 mm	35685	S.S/Ti
Denham Pin	Length 225 mm Dia 4.0 to 6.0 mm	35685	S.S/Ti
Cerclage wire	Length 280 mm 17 to 21 SWG	35685	S.S/Ti
ORTHOPAEDICS NAILS			
Jweet Nail 120*	-	33187	S.S/Ti
Kuntseher Clover Leaf Nail	Length 20 to 48 cm Dia 07 to 13 mm	33187, 38152	S.S/Ti



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DEVICE NAME	DEVICE MODEL	GMDN CODE	MATERIAL
Bend Kuntseher Clover Leaf Nail	Length 26 to 44 cm Dia 07 to 10 mm	33187, 38152	S.S/Ti
Square Nail For Radius	Length 18 to 30 cm Dia 1.5 to 4.0 mm	47762	S.S/Ti
Square Nail For Ulan	Length 18 to 30 cm Dia 1.5 to 4.0 mm	47762	S.S/Ti
Universal Tibia Nail Model 1	Length 30 to 38 cm Dia 8.0 to 10.0 mm	38152	S.S/Ti
Universal Femoral Nail Model 1	Length 34 to 44 cm Dia 9.0 to 12.0 mm	33187	S.S/Ti
Universal Tibia Nail Model 2	Length 30 to 38 cm Dia 8.0 to 10.0 mm	38152	S.S/Ti
Universal Femoral Nail Model 2	Length 34 to 44 cm Dia 9.0 to 12.0 mm	33187	S.S/Ti
Rush Nail	Length 18 to 30 cm Dia 2.0 to 4.0 mm	47762	S.S/Ti

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DEVICE NAME	DEVICE MODEL	GMDN CODE	MATERIAL
PFN Nail	Length 30 to 38 cm Dia 6.0 to 14.0 mm	38152	S.S/Ti
Supra Condylar nail (five holes & multiple holes)	Length 30 to 38 cm Dia 10.0 to 13.0 mm	38152	S.S/Ti
Humorous nail	Length 30 to 38 cm Dia 6.7 & 7.5 mm	38152	S.S/Ti
Reconstruction Nail (right & left)	Length 30 to 38 cm Dia 9.0 to 13.0 mm	38152	S.S/Ti
SPINAL IMPLANTS			
Mono Axial SCREW 4.0 , 4.5 DIA	Length 20 to 60 mm	46651	Ti
Mono Axial Screw 5.0, 5.0 mm Dia	Length 20 to 60 mm	46651	Ti
Mono Axial Screw 6.0, 6.5 mm dia	Length 20 to 60 mm	46651	Ti
Poly Axial Screw 4.0 mm, 4.5 mm Dia	Length 20 to 60 mm	46651	Ti
Poly Axial Screw 5.0 mm, 5.5 mm Dia	Length 20 to 60 mm	46651	Ti

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DEVICE NAME	DEVICE MODEL	GMDN CODE	MATERIAL
Poly Axial Screw 6.0 mm, 6.5 mm Dia	Length 20 to 60 mm	46651	Ti
Mono Axial Single Lock Screw 4.0,4.5 mm dia	Length 20 to 60 mm	46651	Ti
Mono Axial Single Lock Screw 5.0,5.5 mm dia	Length 20 to 60 mm	46651	Ti
Mono Axial Single Lock Screw 6.0,6.5 mm dia	Length 20 to 60 mm	46651	Ti
Poly Axial Single Lock Screw 4.0,4.5 mm dia	Length 20 to 60 mm	46651	Ti
Poly Axial Single Lock Screw 5.0,5.5 mm dia	Length 20 to 60 mm	46651	Ti
Poly Axial Single Lock Screw 6.0,6.5 mm dia	Length 20 to 60 mm	46651	Ti
Mini Poly Axial Single Lock Screw 2.5 mm dia	Length 20 to 30 mm	46651	Ti
Mini Poly Axial Single Lock Screw 3.0 mm dia	Length 20 to 30 mm	46651	Ti
Mini Poly Axial Single Lock Screw 3.0 , 3.5 mm dia	Length 20 to 30 mm	46651	Ti
Reduction Screw 5.0 , 5.0 mm	Length 20 to 60 mm	46651	Ti

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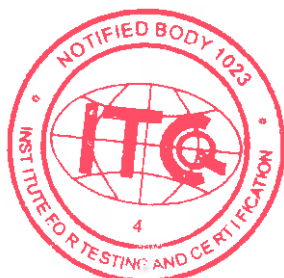
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DEVICE NAME	DEVICE MODEL	GMDN CODE	MATERIAL
Reduction Screw 6.0 , 6.5 mm	Length 20 to 60 mm	46651	Ti
Pedicle Hook	-	61325	Ti
Laminar Hook Reduce Distance	-	61325	Ti
Laminar hook Angle Blade	-	61325	Ti
Laminar hook Narrow Blade	-	61325	Ti
Laminar Hook Wide Blade	-	61325	Ti
Transverse Connectors	-	61325	Ti
Cervi Link Plate	25 to 50 mm	46653	Ti
Bone screw For Cervilink Plate 4.0 mm	10 to 18 mm	46651	Ti
Lock Screw For Cervilink Plate	10 to 18 mm	46651	Ti
Cross Link Hook	10 to 18 mm	61325	Ti
Pliff Cage	3mm to 15 mm	61325	Ti
TIiff Cage	3mm to 15 mm	61325	Ti
Universal cage Spine	3mm to 15 mm	61325	Ti
Expandable cage	8mm to 22 mm	61325	Ti
Eco Cage	8mm to 22 mm	61325	Ti

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DEVICE NAME	DEVICE MODEL	GMDN CODE	MATERIAL
Kidney Cage	3mm to 15 mm	61325	Ti
Cage Model 1	3mm to 15 mm	61325	Ti
Cage Model 2	3mm to 15 mm	61325	Ti
Cage Model 3	-	61325	Ti
Cage Model 4	-	61325	Ti
Staples	-	61325	Ti



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Certificate History:

Revision	Date	Reference Number	Action
	2018-09-11	803602591	Certification



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