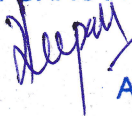
	Annex 08	Rev. 02
	Declaration Of Conformity	Dated: 05.12.2017

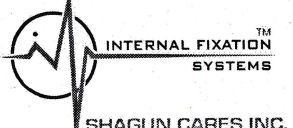
UID No. :DOC_Orthopeadic Implants-01

Manufacture's Name:	Shagun Cares Inc.
Manufacture's Address:	Manufacturing Address: C-27, D.S.I.D.C Industrial Complex, Rohtak Road, Nangloi, New Delhi 110041, India. Ware House: Sector B-3, Plot No. C 22, Tronica City Industrial Area , Ghaziabad 201102, Uttar Pradesh, India
Product Name:	Orthopedic Implants (Refer Annex I – Product List) - Bone Screws - Bone Plates - Locking Plates - Maxillofacial Implants, - Spinal Implants - Wires & Pins - Nails
Brand Name	Internal Fixation Systems Ortho FIXOR Shagun Cares
Applicable Directive	Annex II – Full Quality Assurance of 93/42/EEC Medical Device Directives as amended 2007/47/EC excluding Section IV
Classification	IIb – (Rule 8 – Surgically invasive long term implantable devices)
Applicable Standards	Refer Annex-II for Applicable Standards
EU Rep	Implant Manufacturing British Company Limited 30-34, New Bridge Street, London, U.K. Contact Person: Ms. Nidhi Tel: 020-74294100
Notified Body	ITC (Notified Body No 1023)
EC Certificate No.	
Valid Till	
The undersigned declares that the above-named products conform to the above Directives and Standards as applicable on the devices.	
Authorized Signatory Name: Mr. Deepak Gupta Director, Shagun Cares Inc. Date: 6th December 2017	

For SHAGUN CARES INC.

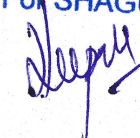


Auth. Signatory

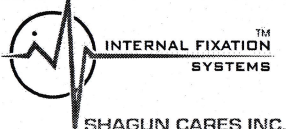
	Annex-I	Rev. 01
	Product List	Dated: 10.07.2017

Locking bolt 7.5 mm	30 mm to 100 mm	56642	IIb	S.S/Ti	8	Non-Sterile	MD 202
ORTHOPAEDIC BONE PLATES							
MINI STRAIGHT PLATE FOR 2.0 MM SCREW	2 holes to 8 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
MINI L- PLATE	Left & right	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
DCP for 2.7mm screw	2 holes to 8 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
L – plate for 2.7 mm screw	Left & right	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
T Plates For 2.7 mm screw	2 holes to 3 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Straight Reconstruction Plate for 2.7 mm screws	5 holes to 24 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Quarter Tubular Plate for 2.7 mm screw	2 holes to 10 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
One – third tubular plate	2 holes to 12 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Small T plate Oblique Angled	3 holes to 10 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
LC DCP 3.5 mm	3 holes to 12 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Y Reconstruction Plate	3 holes to 10 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
DCP plate 3.5 mm	2 holes to 12 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Straight Reconstruction Plate 3.5 mm	5 holes to 22 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Small T plate right angle	3 holes to 10 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Straight Reconstruction Plate 4.5 mm	5 holes to 18 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Semi Tubular Plate for 4.5 mm screw	4 holes to 18 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
LC DCP 4.5 mm Broad	6 holes to 18 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
DCP 4.5 mm Broad	6 holes to 20 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
DCP 4.5 mm Narrow	4 holes to 18 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
T Buttress Plate 4.5 mm	3 holes to 10 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
T plate 4.5 mm	3 holes to 10 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Curved Reconstruction Plate 3.5 mm	3 holes to 18 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Clover leaf Plate	3 holes to 10 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Calcaneal Plate 3.5 mm	60 mm to 90 mm	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Narrow Lengthening Plate 4.5 mm	4 holes to 18 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Spoon Plate	4 holes to 7 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Cobra Head Plate	8 holes to 16 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202

For SHAGUN CARES INC.



Auth. Signatory

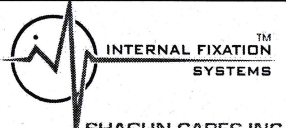
	Annex-I	Rev. 01
	Product List	Dated: 10.07.2017

Hook Plate	6 holes to 7 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Angled Blade Plate 90*	4 holes to 5 holes (60 mm length to 85 mm length)	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Angle Blade Plate 120*	4 holes to 5 holes (60 mm length to 85 mm length)	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
DHS Barrel Plate 120*	4 holes to 18 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Steffee Plate	1 holes to 5 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Condylar Plate 95* for Adults	5 holes to 14 holes Blade Length 50 to 80 mm	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Condylar Buttress Plate 4.5 mm	6 holes to 16 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Lateral Tibia Head Buttress Plate 4.5 mm	6 holes to 16 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
L buttress Plate 4.5 mm Left & Right	3 holes to 14 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Angled Blade Plate 130* For Adults	4 holes to 12 holes Blade Length 50 to 80mm	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
DHS Plate 130*	4 holes to 16 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
DHS Plate 135*	4 holes to 16 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
DCS Plate 95*	6 holes to 18 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
H plate for Cervical Spine	5 holes to 11 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Semi tubular plate 3.5 mm	4 holes to 12 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
MAXILLOFACIAL IMPLANTS							
Three Dimensional Bone Plate Rectangular		46642	IIb	S.S/Ti	8	Non-Sterile	MD 202
Mini Bone Plate Continuous Plate	4 holes to 24 holes	46642	IIb	S.S/Ti	8	Non-Sterile	MD 202
Orbital plate continues plate	4 holes to 16 holes	46642	IIb	S.S/Ti	8	Non-Sterile	MD 202
Reconstruction Plate for Mandibles	4 holes to 30 holes	46642	IIb	S.S/Ti	8	Non-Sterile	MD 202
Splitfix Plate		46642	IIb	S.S/Ti	8	Non-Sterile	MD 202
T plate with bar		46642	IIb	S.S/Ti	8	Non-Sterile	MD 202

For SHAGUN CARES INC.

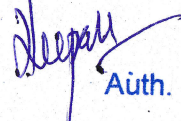
Deepu

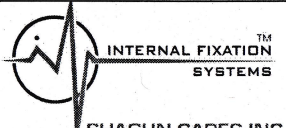
Auth. Signatory

	Annex-I	Rev. 01
	Product List	Dated: 10.07.2017

TMJ Condyle		46642	IIb	S.S/Ti	8	Non-Sterile	MD 202
TMJ condyle With Reconstruction Angular Plate		46642	IIb	S.S/Ti	8	Non-Sterile	MD 202
Wire Meshes		46267, 46268	IIb	S.S/Ti	8	Non-Sterile	MD 202
X Plate		46642	IIb	S.S/Ti	8	Non-Sterile	MD 202
Y plate		46642	IIb	S.S/Ti	8	Non-Sterile	MD 202
Z plate		46642	IIb	S.S/Ti	8	Non-Sterile	MD 202
Nose Plate X shape	10 holes	46642	IIb	S.S/Ti	8	Non-Sterile	MD 202
Maxilla Plate Left n Right 1.5 mm Dia	1.5 mm Dia	46642	IIb	S.S/Ti	8	Non-Sterile	MD 202
Nose Plate	12 holes	46642	IIb	S.S/Ti	8	Non-Sterile	MD 202
Mandible Plate		46642	IIb	S.S/Ti	8	Non-Sterile	MD 202
Chine Plate	2.0 mm	46642	IIb	S.S/Ti	8	Non-Sterile	MD 202
Chin Plate 2.0 Single Curved		46642	IIb	S.S/Ti	8	Non-Sterile	MD 202
Chin Plate 2.0 Double Curved		46642	IIb	S.S/Ti	8	Non-Sterile	MD 202
Mini straight plate for 2.0mm screw	2 holes to 8 holes	46642	IIb	S.S/Ti	8	Non-Sterile	MD 202
Mini L plate	Left and Right	46642	IIb	S.S/Ti	8	Non-Sterile	MD 202
Mini DCP 2.0 mm	4 holes to 8 holes	46642	IIb	S.S/Ti	8	Non-Sterile	MD 202
Mini T Plate for 2.0mm screw		46642	IIb	S.S/Ti	8	Non-Sterile	MD 202
ORTHOPAEDICS LOCKING PLATES							
1/3 Tubular Locking Plate	2 to 12 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Small T Plate Right Angle Locking Plate	3 to 8 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Small T Oblique Angled Locking Plate	3 to 8 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
3.5 Mm LCDCP Locking Plate	2 to 12 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Mini T Locking Plate	2 to 8 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Mini L Locking Plate Left And Right	3 to 8 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Mini T Oblique Locking Plate Left & Right	2 to 12 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Mini Straight Locking Plate	4 to 6 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
¼ Quarter Tubular Locking Plate	2 to 10 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
¼ Quarter Tubular Locking Plate For 2.7 mm Screw	4 to 6 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202

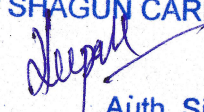
For SHAGUN CARES INC.

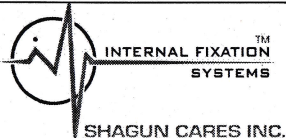

Auth. Signatory

	Annex-I	Rev. 01
	Product List	Dated: 10.07.2017

Straight Reconstruction Plate For 2.7 mm Locking Screws	5 to 24 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Straight Reconstruction Plate For 3.5 mm Locking Screws	5 to 22 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Straight Reconstruction Plate For 4.5 mm Locking Screws	4 to 16 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Clover Leaf Locking Plate 3.5 mm	3 to 6 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Clover Leaf Locking Plate 4.5 mm	3 to 12 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
4.5 mm Narrow LCDCP Locking Plate	4 to 22 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
4.5 mm Broad LCDCP Locking Plate	4 to 22 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
2.7 mm LCDCP Locking Plate	4 to 22 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
T Locking Plate 4.5 mm	3 to 12 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
L Buttress Locking Plate Left & Right	3 to 6 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Proximal Lateral Tibia Locking Plate Left & Right	5 to 13 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Distal Femur Locking Plate Left & Right	5 to 13 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
3.5 Semi Tubular Locking Plate	2 to 12 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
5.0 mm Semi Tubular Locking Plate	4 to 14 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Calcaneal Locking Plate 3.5 mm	64 mm to 81 mm	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Calcaneal Locking Plate 5.0 mm	64 mm to 81 mm	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
DHS Locking Plate 120 To 150*	2 to 14 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
DCS Locking Plate 90*	4 to 22 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Distal Humorous Locking Plate Without Support	3 to 14 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Distal Humorous Locking Plate With Support	3 to 14 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Oleaconon Locking Plate Left & Right	2 to 12 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Distal Radius Locking Plate (assorted type & left-right)	3 to 12 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Proximal Femur Locking Plate Left & Right	2 to 16 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Proximal Femur Locking Hook Plate Left & Right	2 to 16 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Distal Tibia Locking Plate Left & Right	4 to 14 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Proximal Humorous Locking Plate	3 to 12 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Metaphyseal Plate 3.5 mm	6 to 18 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202

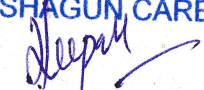
For SHAGUN CARES INC.


Auth. Signatory

	Annex-I	Rev. 01
	Product List	Dated: 10.07.2017

Metaphyseal Plate 4.5 mm	3 to 15 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Clavicle hook plate	4 to 7 holes (depth 12 mm to 18 mm)	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Philos Proximal humeral plate	5 to 12 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Superior Anterior clavicle plate 3.5 mm	4 to 14 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Superior Anterior clavicle plate 2.7/3.5 mm	3 to 8 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Metaphyseal Distal Medial hemispherical 3.5 mm	4 to 20 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Distal Medial Humeral	3 to 14 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Pediatric Hip plate	Angles 100* to 150*	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Tomofix plate	3 to 4 holes (left-right)	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Proximal Tibia Plate 3.5 mm	4 to 16 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Proximal Tibia Plate 5.0 mm	4 to 14 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Medial Proximal Tibia 3.5 mm	4 to 20 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Medial Proximal Tibia 5.0 mm	4 to 16 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Distal tibia plate	4 to 14 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Distal tibia Without Tab	4 to 14 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Anterolateral distal tibia	5 to 21 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Pilon plate	7 to 9 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Two column Distal radius	2 to 13 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Adaption plate	12 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Condylar adaption plate	7 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
T adaption plate	7 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202
Y adaption plate	7 holes	61573	IIb	S.S/Ti	8	Non-Sterile	MD 202

For SHAGUN CARES INC.


Auth. Signatory