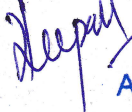
	Annex 08	Rev. 02
	Declaration Of Conformity	Dated: 05.12.2017

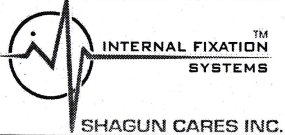
UID No. :DOC_Orthopedic Implants-01

Manufacturer's Name:	Shagun Cares Inc.
Manufacturer'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) <ul style="list-style-type: none"> - 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	

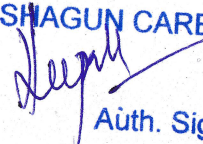
For SHAGUN CARES INC.

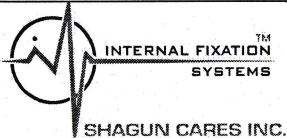


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	Annex-I	Rev. 01
	Product List	Dated: 10.07.2017

ORTHOPAEDICS WIRES AND PINS							
Washer for 4.0 mm Cancellous screw		61670	IIb	S.S/Ti	8	Non-Sterile	MD 202
Washer for 4.5 mm Malleolar screw and 6.5 mm Cancellous screw		61670	IIb	S.S/Ti	8	Non-Sterile	MD 202
Stainless Steel Wire	16 to 30 SWG	35685	IIb	S.S/Ti	8	Non-Sterile	MD 202
Kirsehner wire With trocar Tip	Length 70 to 400 cm Dia 0.8 to 3.0 mm	35685	IIb	S.S/Ti	8	Non-Sterile	MD 202
Hart shell	75 to 250 mm	35685	IIb	S.S/Ti	8	Non-Sterile	MD 202
Drummer Wire	18 to 20 SWG	35685	IIb	S.S/Ti	8	Non-Sterile	MD 202
Harrington Rod & hooks	Length 25 to 200 mm	61325	IIb	S.S/Ti	8	Non-Sterile	MD 202
Stainmaan Pin	Length 150 to 300mm Dia 3.0 to 5.0 mm	35685	IIb	S.S/Ti	8	Non-Sterile	MD 202
Denham Pin	Length 225mm Dia 4.0 to 6.0 mm	35685	IIb	S.S/Ti	8	Non-Sterile	MD 202
Cerclage wire	Length 280 mm 17 to 21 SWG	35685	IIb	S.S/Ti	8	Non-Sterile	MD 202
ORTHOPAEDICS NAILS							
Jweet Nail 120*		60411	IIb	S.S/Ti	8	Non-Sterile	MD 202
Kuntseher Clover Leaf Nail	Length 20 to 48 cm Dia 07 to 13 mm	60411	IIb	S.S/Ti	8	Non-Sterile	MD 202
Bend Kuntseher Clover Leaf Nail	Length 26 to 44 cm Dia 07 to 10 mm	60411	IIb	S.S/Ti	8	Non-Sterile	MD 202
Square Nail For Radius	Length 18 to 30 cm Dia 1.5 to 4.0 mm	60411	IIb	S.S/Ti	8	Non-Sterile	MD 202
Square Nail For Ulan	Length 18 to 30 cm Dia 1.5 to 4.0 mm	60411	IIb	S.S/Ti	8	Non-Sterile	MD 202
Universal Tibia Nail Model 1	Length 30 to 38 cm	60411	IIb	S.S/Ti	8	Non-Sterile	MD 202


For SHAGUN CARES INC.

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	Annex-I	Rev. 01
	Product List	Dated: 10.07.2017

	Dia 8.0 to 10.0 mm						
Universal Femoral Nail Model 1	Length 34 to 44 cm Dia 9.0 to 12.0 mm	60411	IIb	S.S/Ti	8	Non-Sterile	MD 202
Universal Tibia Nail Model 2	Length 30 to 38 cm Dia 8.0 to 10.0 mm	60411	IIb	S.S/Ti	8	Non-Sterile	MD 202
Universal Femoral Nail Model 2	Length 34 to 44 cm Dia 9.0 to 12.0 mm	60411	IIb	S.S/Ti	8	Non-Sterile	MD 202
Rush Nail	Length 18 to 30 cm Dia 2.0 to 4.0 mm	60411	IIb	S.S/Ti	8	Non-Sterile	MD 202
PFN Nail	Length 30 to 38 cm Dia 6.0 to 14.0 mm	60411	IIb	S.S/Ti	8	Non-Sterile	MD 202
Supra Condylar nail (five holes & multiple holes)	Length 30 to 38 cm Dia 10.0 to 13.0 mm	60411	IIb	S.S/Ti	8	Non-Sterile	MD 202
Humorous nail	Length 30 to 38 cm Dia 6.7 & 7.5 mm	60411	IIb	S.S/Ti	8	Non-Sterile	MD 202
Reconstruction Nail (right & left)	Length 30 to 38 cm Dia 9.0 to 13.0 mm	60411	IIb	S.S/Ti	8	Non-Sterile	MD 202
SPINAL IMPLANTS							
Mono Axial SCREW 4.0 , 4.5 DIA	Length 20 to 60 mm	61325	IIb	Ti	8	Non-Sterile	MD 202
Mono Axial Screw 5.0, 5.0 mm Dia	Length 20 to 60 mm	61325	IIb	Ti	8	Non-Sterile	MD 202
Mono Axial Screw 6.0, 6.5 mm dia	Length 20 to 60 mm	61325	IIb	Ti	8	Non-Sterile	MD 202
Poly Axial Screw 4.0 mm, 4.5 mm Dia	Length 20 to 60 mm	61325	IIb	Ti	8	Non-Sterile	MD 202
Poly Axial Screw 5.0 mm, 5.5 mm Dia	Length 20 to 60 mm	61325	IIb	Ti	8	Non-Sterile	MD 202
Poly Axial Screw 6.0 mm, 6.5 mm Dia	Length 20 to 60 mm	61325	IIb	Ti	8	Non-Sterile	MD 202
Mono Axial Single Lock Screw 4.0,4.5 mm dia	Length 20 to 60 mm	61325	IIb	Ti	8	Non-Sterile	MD 202
Mono Axial Single Lock Screw 5.0,5.5 mm dia	Length 20 to 60 mm	61325	IIb	Ti	8	Non-Sterile	MD 202
Mono Axial Single Lock Screw 6.0,6.5 mm dia	Length 20 to 60 mm	61325	IIb	Ti	8	Non-Sterile	MD 202
Poly Axial Single Lock Screw 4.0,4.5 mm dia	Length 20 to 60 mm	61325	IIb	Ti	8	Non-Sterile	MD 202
Poly Axial Single Lock Screw 5.0,5.5 mm dia	Length 20 to 60 mm	61325	IIb	Ti	8	Non-Sterile	MD 202

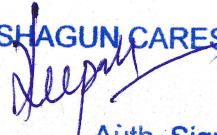
For SHAGUN CARES INC.

Deepak
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	Annex-I	Rev. 01
	Product List	Dated: 10.07.2017

Poly Axial Single Lock Screw 6.0,6.5 mm dia	Length 20 to 60 mm	61325	IIb	Ti	8	Non-Sterile	MD 202
Mini Poly Axial Single Lock Screw 2.5 mm dia	Length 20 to 30 mm	61325	IIb	Ti	8	Non-Sterile	MD 202
Mini Poly Axial Single Lock Screw 3.0 mm dia	Length 20 to 30 mm	61325	IIb	Ti	8	Non-Sterile	MD 202
Mini Poly Axial Single Lock Screw 3.0 , 3.5 mm dia	Length 20 to 30 mm	61325	IIb	Ti	8	Non-Sterile	MD 202
Reduction Screw 5.0 , 5.0 mm	Length 20 to 60 mm	61325	IIb	Ti	8	Non-Sterile	MD 202
Reduction Screw 6.0 , 6.5 mm	Length 20 to 60 mm	61325	IIb	Ti	8	Non-Sterile	MD 202
Pedicle Hook		61325	IIb	Ti	8	Non-Sterile	MD 202
Laminar Hook Reduce Distance		61325	IIb	Ti	8	Non-Sterile	MD 202
Laminar hook Angle Blade		61325	IIb	Ti	8	Non-Sterile	MD 202
Laminar hook Narrow Blade		61325	IIb	Ti	8	Non-Sterile	MD 202
Laminar Hook Wide Blade		61325	IIb	Ti	8	Non-Sterile	MD 202
Transverse Connectors		61325	IIb	Ti	8	Non-Sterile	MD 202
Cervi Link Plate	25 to 50 mm	61325	IIb	Ti	8	Non-Sterile	MD 202
Bone screw For Cervilink Plate 4.0 mm	10 to 18 mm	61325	IIb	Ti	8	Non-Sterile	MD 202
Lock Screw For Cervilink Plate	10 to 18 mm	61325	IIb	Ti	8	Non-Sterile	MD 202
Cross Link Hook	10 to 18 mm	61325	IIb	Ti	8	Non-Sterile	MD 202
Pliff Cage	3mm to 15 mm	61325	IIb	Ti	8	Non-Sterile	MD 202
Tliff Cage	3mm to 15 mm	61325	IIb	Ti	8	Non-Sterile	MD 202
Universal cage Spine	3mm to 15 mm	61325	IIb	Ti	8	Non-Sterile	MD 202
Expandable cage	8mm to 22 mm	61325	IIb	Ti	8	Non-Sterile	MD 202
Eco Cage	8mm to 22 mm	61325	IIb	Ti	8	Non-Sterile	MD 202
Kidney Cage	3mm to 15 mm	61325	IIb	Ti	8	Non-Sterile	MD 202
Cage Model 1	3mm to 15 mm	61325	IIb	Ti	8	Non-Sterile	MD 202
Cage Model 2	3mm to 15 mm	61325	IIb	Ti	8	Non-Sterile	MD 202
Cage Model 3		61325	IIb	Ti	8	Non-Sterile	MD 202
Cage Model 4		61325	IIb	Ti	8	Non-Sterile	MD 202
Staples		61325	IIb	Ti	8	Non-Sterile	MD 202

For SHAGUN CARES INC.



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