

Certificate of Compliance



We hereby declare that the technical file of product complied with the requirements of EC directive 93/42/EEC Medical Device Directive (MDD).

Certificate No.: CE-3571

Manufacturer

Name : **Shagun Cares Inc.**

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

**Warehouse: Sector B-3, Plot No. C 22, Tronica City Industrial
Area, Ghaziabad 201102, Uttar Pradesh, India**

Product Name: **Orthopaedic External Fixators
As Per Annexure-I- III**

Complies with the requirements applicable to it

The Certification body has performed an audit of the above product quality system covering the design, manufacture and final inspection of the certified product. The quality system has been assessed, approved and is subject to continuous surveillance according to Directive EC directive 93/42/EEC Medical Device Directive (MDD).

This certificate is issued under the following conditions:

1. It applies only to the quality system maintained in the manufacture of above referenced models and it does not substitute the design or type-examination procedures, if requested.
2. The certificate remains valid until the manufacturing conditions or the quality systems are not changed.
3. The certificate validity is conditioned by positive results of surveillance audits.
4. The CE mark as shown above can be used, under the responsibility of the manufacturer, after completion of an EC Declaration of conformity and compliance with all relevant EC Directives. The statement is based on a single evaluation of one sample of above mentioned product. It does not imply an assessment of the whole production.

Validity of this certificate can be verified at www.ukcertifications.co.uk/verify

Date of Certification 23rd August 2018

1st Surveillance Audit Due 22nd August 2019

2nd Surveillance Audit Due 22nd August 2020

Certificate Expiry (subject to the company maintaining its system to the required standard) 22nd August 2021



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Appendix-I

Appendix to Certificate no.:- CE-3571

Manufacturer :

Shagun Cares Inc.

Product :

Orthopaedic External Fixators.



This certificate referred to above covers the following products like:

Sr. No.	Product	Range	Sizes/Length
I	External Fixators	Single Adjustable Clamp Universal Joint	
		Trans Tibia Clamp	
		Tube to tube Clamp	
		Tubular Clamp	4x4.mm , 4 x2.5 mm
		Twin Adjustable Clamp	
		Connecting Clamp S.S and Carbone fiber , Aluminium	8.0x8.0 mm
		Asculap Clamp S.S And Carbone fiber , Aluminium	5 x8.0 mm
		Tubes 11 mm Dia S.S and Carbone fiber , Aluminium	100 to 450 mm
		Tubes 8.0 mm dia S.S And Carbon Fiber Aluminium	100 to 450 mm
		Connecting Bar 4.0 mm dia S. s and Carbon Fiber Aluminium	30 to 100 mm
		Schanz pin 4.5 mm to 5.0 mm	170 to 200 mm
		Schanz Pin 4.0 x3.5 mm	125 to 150 mm
		Schanz Pin 2.5 x2.5 mm	100 to 150 mm
		Threaded Rods with tubes 4.0 mm	
		Spanner T handle Type	8.0 to 11 mm
		Combination Wrench Width across 10/11	
		Threaded Rod	50 to 500 mm
		Olive wire (bayonet Point)	
		Post Female	2 to 5 holes
		Short Connection Plate S.S And Carbone Fiber , Aluminium	2 to 10 holes

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Appendix-II

Appendix to Certificate no.:- CE-3571

Manufacturer :

Shagun Cares Inc.

Product :

Orthopaedic External Fixators.



This certificate referred to above covers the following products like:

Sr. No.	Product	Range	Sizes/Length
		Post Male	2 to 5 holes
		Rencho Cube	1 to 5 holes
		Hinge Female	
		Twisted Plate	2 to 6 holes
		Hinge Male	
		Bushing	
		Square nut	
		Slotted Washer	
		Connection Bolt	10 to 30 mm
		Nut	
		Wire Fixation Bolt	
		Trocar Point wire	
		Bayonet Point wire	
		Half Ring S.S and Carbon Fiber And Aluminium	80 to 240 mm
		5/8 rings S.S and Carbon Fiber And Aluminium	120 to 240 mm
		Italian Femoral Arches S.S and Carbon Fiber And Aluminium	
		Double Pin Clamp	
		Open Clamp	
		Twisted adjustable clamp curved	
		Transverse Clamp	
		Self Holding Clamp	

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Appendix-III

Appendix to Certificate no.:- CE-3571

Manufacturer :

Shagun Cares Inc.

Product :

Orthopaedic External Fixators.



This certificate referred to above covers the following products like:

Sr. No.	Product	Range	Sizes/Length
		Small Connecting clamp	
		Multi pin Fixation Clamp	
		Omega Ring S.S and Carbon Fiber And Aluminium	
		Graduated Telescopic rod	
		Oblique support	
		Single Pin Fixation Clamp	
		Threaded socket	
		Wire tensioner	
		Clamp For Forearm	
		Compression And Distraction device	
		Schanz pin Introducer	
		Limb Lengthening Fixations	Small , Medium , Large
		Wrist Fixator	
		Distracter Large	
		Distracter Small	
		Mini Distracter	
		Distraction / Compression Assembly for Radius / Wrist Joint	
		Dynamic Axial Limbs Lengthening fixator	Small , Medium , Large
		Mini Rail System	
		Calcaneal External Fixator	
		Penning Mini Fixator	
		Lock Ring Fixator	
		Articulated Angle Fixation	

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