



Certification & Inspection

# Certificate of Compliance

Certificate Number: UQ-10321

This is to certify that

**SHAGUN CARES INC.**

at

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

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

Has successfully implemented the Quality management System and been found working satisfactorily as per the norms of "Good Manufacturing Practice" as laid down by "World Health Organisation" which has been in conformance to the requirements of

## WHO-GMP

Scope: Manufacturer and Supply of Orthopaedics, Spinal, Arthroscopy, Oncology and Joints Replacement Implants, Prosthesis and Instruments

This certificate is issued under the following conditions:

1. It applies only to the quality system maintained in the manufacture of above referenced Models Products.
2. The certificate remains valid until the manufacturing conditions or the quality systems are changed and is subject to continuous surveillance according to the WHO-GMP Guidelines
3. The certificate validity is conditioned by positive results or surveillance audits.

Validity of this certificate can be verified at [www.ukcertifications.co.uk/verify](http://www.ukcertifications.co.uk/verify)

Date of Certification

25<sup>th</sup> May 2018

Date of this Certificate

24<sup>th</sup> May 2019

1<sup>st</sup> Surveillance Audit Due

24<sup>th</sup> May 2020

Certificate Expiry (subject to the company maintaining its system to the required standard)

24<sup>th</sup> May 2021

*Daniel..*

Authorised Signatory



This certificate is the property of UK Certification & Inspection Limited and shall be returned immediately on request.  
71-75 Shelton Street, Covent Garden, London, WC2H 9JQ, United Kingdom  
Website:- [www.ukcertifications.co.uk](http://www.ukcertifications.co.uk), email:- [info@ukcertifications.co.uk](mailto:info@ukcertifications.co.uk)  
Company No. 10517947





Notified Body No 1023  
**INSTITUTE FOR TESTING AND CERTIFICATION, Inc.**  
Zlín, Czech Republic – [www.itczlin.cz](http://www.itczlin.cz)

## EC CERTIFICATE

**No. 12 0339 QS/NB**

issued in compliance with the Council Directive 93/42/EEC as amended, which is implemented by the Czech Government Order No. 336/2004 (Collection of Laws), certifies that the products – medical devices of Class IIa and IIb,

### **Orthopaedic Implants, Spinal Implants, External Fixators and Orthopaedic Instruments**

(For detailed specification refer to Annex, pages 2 - 36)

manufactured by company

#### **Shagun Cares Inc.**

Registered site: Office B-23, Madipur, Main Road, New Delhi 110063, India.

Work site: Plot Number C-22, Sector B-3, Tronica City Industrial Area, Loni Border, Ghaziabad, Uttar Pradesh 201102, India.

are manufactured under conditions fulfilling the quality system requirements of Annex II, Section 3.2. of the Directive 93/42/EEC, as amended.

The Notified Body No. 1023 has performed an audit of the above products quality system covering the design, manufacture and final inspection of the certified products. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex II, Sections 3.3. and 5. of the Directive 93/42/EEC. The detailed description of the system parts, requirements and measures applied by the manufacturer are presented in the Final Report No. 803601474/2012, which is enclosed to this Certificate.

#### *Condition of this Certificate use and related information:*

1. It applies only to the quality system maintained in the manufacture of above referenced models of medical devices 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 system are changed but until the **26<sup>th</sup> April 2017** at the latest.
3. The Certificate validity is conditioned by positive results of surveillance audits.
4. After fulfilling the relevant EU legislation, the manufacturer shall affix to each medical device, of the above referenced models, the CE-marking followed by the number of the Notified Body according to this example:



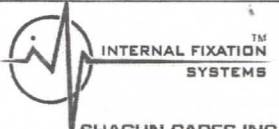
Issued in Zlín, on 27<sup>th</sup> April 2012



RNDr. Radomír Čevelík

Representative of the Notified Body No. 1023

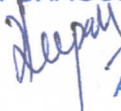


	Annex 08	Rev. 02
	Declaration Of Conformity	Dated: 05.12.2017

UID No. :DOC\_Orthopaedic Implants-01

<b>Manufacture's Name:</b>	Shagun Cares Inc.
<b>Manufacture's Address:</b>	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
<b>Product Name:</b>	Orthopedic Implants (Refer Annex I – Product List) <ul style="list-style-type: none"> <li>- Bone Screws</li> <li>- Bone Plates</li> <li>- Locking Plates</li> <li>- Maxillofacial Implants,</li> <li>- Spinal Implants</li> <li>- Wires &amp; Pins</li> <li>- Nails</li> </ul>
<b>Brand Name</b>	Internal Fixation Systems Ortho FIXOR Shagun Cares
<b>Applicable Directive</b>	Annex II – Full Quality Assurance of 93/42/EEC Medical Device Directives as amended 2007/47/EC excluding Section IV
<b>Classification</b>	IIb – (Rule 8 – Surgically invasive long term implantable devices)
<b>Applicable Standards</b>	Refer Annex-II for Applicable Standards
<b>EU Rep</b>	Implant Manufacturing British Company Limited 30-34, New Bridge Street, London, U.K. Contact Person: Ms. Nidhi Tel: 020-74294100
<b>Notified Body</b>	ITC (Notified Body No 1023)
<b>EC Certificate No.</b>	
<b>Valid Till</b>	
The undersigned declares that the above-named products conform to the above Directives and Standards as applicable on the devices.	
Authorized Signatory <b>Name: Mr. Deepak Gupta</b> <b>Director, Shagun Cares Inc.</b> <b>Date: 6<sup>th</sup> December 2017</b>	

For SHAGUN CARES INC.



Auth. Signatory





UK

# CERTIFICATE OF APPROVAL

Certificate No. 2017-HK-0316

## SHAGUN CARES INC

Factory: C-27, D.S.I.D.C Industrial Complex, Rohtak Road, Nangloi, New Delhi - 110 041, India  
Warehouse: Sector B-3, Plot No. C-22, Tronica City Industrial Area, Ghaziabad – 201 102, Uttar Pradesh, India

This is to certify that the Management System of the above organization has been found to conform to the requirements of the standard :

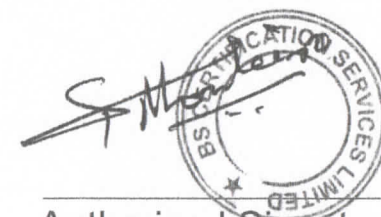
Standard : ISO 13485:2016

Scope of Registration : Manufacture and Supply of Orthopaedic Implants, Spinal Implants and Joints Replacement Prosthesis

Original Approval Date : 26<sup>th</sup> May, 2018

Valid Upto : 25<sup>th</sup> May, 2019

Certification Cycle Year : 2018-2021



Authorized Signatory



This Certificate is valid when confirmed by data listed in the International Register of Quality Assessed Organisations <[www.irqao.org](http://www.irqao.org)>.

The authenticity of this document may be re-affirmed by writing to [info@bscert.hk](mailto:info@bscert.hk). Lack of fulfillment of conditions as set out in the Certification Agreement may render this certificate invalid. Any alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders maybe prosecuted to the fullest extent of law.

**Accreditation Body :** Accreditation Service for Certifying Bodies (Europe) Ltd.  
6, Ferris Place, Boumemouth, Dorset, BH8 0AU, United Kingdom.  
[www.ascb.co.uk](http://www.ascb.co.uk)



**Issuing Authority :** BS Certification Services Limited  
Room 603, 6/F, The Star, 16-18 Yip Shing Street, Kwai Chung, NT, Hong Kong.  
[www.bscert.hk](http://www.bscert.hk)