



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

Date of Certification	25 th May 2018
Date of this Certificate	24 th May 2019
1 st Surveillance Audit Due	24 th May 2020
Certificate Expiry (subject to the company maintaining its system to the required standard)	24 th 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, email:- info@ukcertifications.co.uk
Company No. 10517947

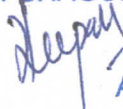


	Annex 08	Rev. 02
	Declaration Of Conformity	Dated: 05.12.2017

UID No. :DOC_Orthopaedic 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.


Auth. Signatory



ISO 13485:2016



UK

CERTIFICATE OF APPROVAL

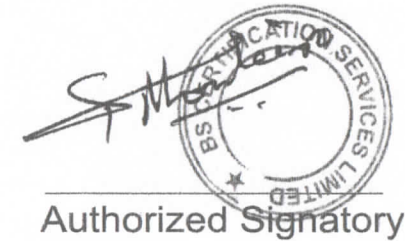
Certificate No. 2017-HK-0316

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 : 26th May, 2018
- Valid Upto : 25th May, 2019
- Certification Cycle Year : 2018-2021



This Certificate is valid when confirmed by data listed in the International Register of Quality Assessed Organisations <www.irqao.org>.

The authenticity of this document may be re-affirmed by writing to 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



Issuing Authority : BS Certification Services Limited
Room 603, 6/F, The Star, 16-18 Yip Shing Street, Kwai Chung, NT, Hong Kong.
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