



Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

EC Certificate - Full Quality Assurance System

No. 18 0310 QS/NB

The quality system of manufacturer

Shagun Cares INC

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

has been certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II excluding (4)

for the following product category(ies):

Orthopaedic Implants

The Notified Body No. 1023 declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subjected to periodical surveillance. For placing on the market of Class III devices covered by this certificate, an EC Design-Examination Certificate according to Annex II (Section 4) is required.

Valid from: 2018-09-11
Valid until: 2023-09-10
First Issued: 2018-09-11
Revision: -



Date: 2018-09-11



Paul Heš
Mgr. Jiří Heš

Representative of the Notified Body No. 1023



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třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 18 0310 QS/NB

issued for manufacturer:

Shagun Cares INC
C-27, D.S.I.D.C Industrial Complex, Rohtak Road, Nangloi, New
Delhi 110041, India

Product(s):

Name: Orthopaedic bone screws
Trade name(s): Internal Fixation Systems, Ortho FIXOR, Shagun Cares
Model(s): see attached table
Class: IIb
GMDN: 56642

Name: Orthopaedic bone plates
Trade name(s): Internal Fixation Systems, Ortho FIXOR, Shagun Cares
Model(s): see attached table
Class: IIb
GMDN: 61573

Name: Maxillofacial implants
Trade name(s): Internal Fixation Systems, Ortho FIXOR, Shagun Cares
Model(s): see attached table
Class: IIb
GMDN: 46642



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issued for manufacturer:

Shagun Cares INC
C-27, D.S.I.D.C Industrial Complex, Rohtak Road, Nangloi, New
Delhi 110041, India

Name: Orthopaedic locking plates
Trade name(s): Internal Fixation Systems, Ortho FIXOR, Shagun Cares
Model(s): see attached table
Class: IIb
GMDN: 61573

Name: Orthopaedic wires and pins
Trade name(s): Internal Fixation Systems, Ortho FIXOR, Shagun Cares
Model(s): see attached table
Class: IIb
GMDN: 61670 (wires), 35685 (pins)

Name: Orthopaedic nails
Trade name(s): Internal Fixation Systems, Ortho FIXOR, Shagun Cares
Model(s): see attached table
Class: IIb
GMDN: 33187, 47762



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Annex to EC Certificate No. 18 0310 QS/NB

issued for manufacturer:

Shagun Cares INC
C-27, D.S.I.D.C Industrial Complex, Rohtak Road, Nangloi, New
Delhi 110041, India

Name:	Spinal implants
Trade name(s):	Internal Fixation Systems, Ortho FIXOR, Shagun Cares
Model(s):	see attached table
Class:	IIB
GMDN:	46651

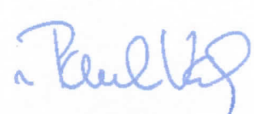
Facility(ies):

Shagun Cares INC
C-27, D.S.I.D.C Industrial Complex, Rohtak Road, Nangloi, New Delhi 110041,
India (legal address and manufacturing site)

Shagun Cares INC
Sector B-3, Plot No. C 22, Tronica City Industrial Area, Ghaziabad 201102, Uttar
Pradesh, India (warehouse)



Date: 2018-09-11
Revision: -


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ISO 13485:2016



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

Current Approval Date* : 22nd May, 2019

Valid Upto : 25th May, 2020

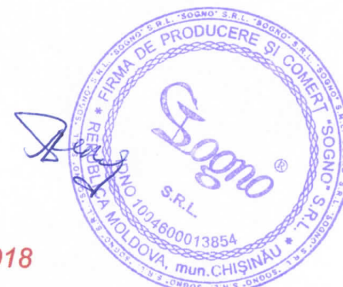
Certification Cycle Year : 2018-2021

* This approval replaces the previous Certificate issued on 26th May, 2018



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 may be prosecuted to the fullest extent of law.



Authorized Signatory



Accreditation Body : Accreditation Service for Certifying Bodies (Europe) Ltd.
6, Ferris Place, Bournemouth, 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
www.bscert.hk



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

25th May 2018

Date of this Certificate

24th May 2019

1st Surveillance Audit Due

24th May 2020

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

24th 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

