



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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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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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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issued for manufacturer:

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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

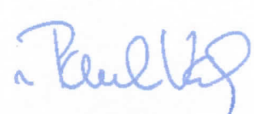
Facility(ies):

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)



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