



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

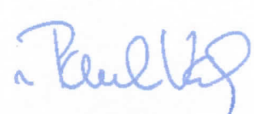
Facility(ies):

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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Variants of the medical device covered by this certificate:

DEVICE NAME	DEVICE MODEL	GMDN CODE	MATERIAL
ORTHOPAEDIC BONE SCREWS			
1.5mm Cortical Screw	6mm to 20mm	56642	S.S/Ti
2.0mm cortical screws	6mm to 20mm	56642	S.S/Ti
2.7mm cortical screw	6mm to 30mm	56642	S.S/Ti
3.5mm cortical screw	10mm to 40mm	56642	S.S/Ti
3.5 mm Cancellous Screw	10 to 40 mm	56642	S.S/Ti
4.0 mm Cancellous screw (short thread)	10 to 60 mm	56642	S.S/Ti
4.0 mm Cancellous screw (Full thread)	10mm to 60 mm	56642	S.S/Ti
4.0 mm Cannulated screw (full thread)	10mm to 60 mm	56642	S.S/Ti
4.0 mm Cannulated screw (short thread)	10 mm to 60 mm	56642	S.S/Ti
4.5 Cortical screw	12mm to 120 mm	56642	S.S/Ti
4.5 mm Cortical screw (Self- Tapping)	12mm to 120 mm	56642	S.S/Ti
6.5 mm Cancellous screw (thread 16 mm)	12 mm to 100 mm	56642	S.S/Ti

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DEVICE NAME	DEVICE MODEL	GMDN CODE	MATERIAL
Quarter Tubular Plate for 2.7 mm screw	2 holes to 10 holes	61573	S.S/Ti
One – third tubular plate	2 holes to 12 holes	61573	S.S/Ti
Small T plate Oblique Angled	3 holes to 10 holes	61573	S.S/Ti
LC DCP 3.5 mm	3 holes to 12 holes	61573	S.S/Ti
Y Reconstruction Plate	3 holes to 10 holes	61573	S.S/Ti
DCP plate 3.5 mm	2 holes to 12 holes	61573	S.S/Ti
Straight Reconstruction Plate 3.5 mm	5 holes to 22 holes	61573	S.S/Ti
Small T plate right angle	3 holes to 10 holes	61573	S.S/Ti
Straight Reconstruction Plate 4.5 mm	5 holes to 18 holes	61573	S.S/Ti
Semi Tubular Plate for 4.5 mm screw	4 holes to 18 holes	61573	S.S/Ti
LC DCP 4.5 mm Broad	6 holes to 18 holes	61573	S.S/Ti

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DEVICE NAME	DEVICE MODEL	GMDN CODE	MATERIAL
Distal Tibia Locking Plate Left & Right	4 to 14 holes	61573	S.S/Ti
Proximal Humorous Locking Plate	3 to 12 holes	61573	S.S/Ti
Metaphyseal Plate 3.5 mm	6 to 18 holes	61573	S.S/Ti
Metaphyseal Plate 4.5 mm	3 to 15 holes	61573	S.S/Ti
Clavicle hook plate	4 to 7 holes (depth 12 mm to 18 mm)	61573	S.S/Ti
Philos Proximal humeral plate	5 to 12 holes	61573	S.S/Ti
Superior Anterior clavicle plate 3.5 mm	4 to 14 holes	61573	S.S/Ti
Superior Anterior clavicle plate 2.7/3.5 mm	3 to 8 holes	61573	S.S/Ti
Metaphyseal Distal Medial humorous 3.5 mm	4 to 20 holes	61573	S.S/Ti
Distal Medial Humeral	3 to 14 holes	61573	S.S/Ti
Pediatric Hip plate	Angles 100* to 150*	61573	S.S/Ti
Tomofix plate	3 to 4 holes (left- right)	61573	S.S/Ti

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