

Certificate of Compliance

CE

We hereby declare that the technical file of product complied with the requirements of EC directive 93/42/EEC Medical Device Directive (MDD).

Certificate No.: CE-3569

Manufacturer

Name : **Shagun Cares Inc.**

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

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

Product Name: **Orthopaedic Joint Replacement (Sterile & Non-Sterile)
As Per Annexure-I**

Complies with the requirements applicable to it

The Certification body has performed an audit of the above product quality system covering the design, manufacture and final inspection of the certified product. The quality system has been assessed, approved and is subject to continuous surveillance according to Directive EC directive 93/42/EEC Medical Device Directive (MDD).

This certificate is issued under the following conditions:

1. It applies only to the quality system maintained in the manufacture of above referenced models 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 systems are not changed.
3. The certificate validity is conditioned by positive results of surveillance audits.
4. The CE mark as shown above can be used, under the responsibility of the manufacturer, after completion of an EC Declaration of conformity and compliance with all relevant EC Directives. The statement is based on a single evaluation of one sample of above mentioned product. It does not imply an assessment of the whole production.

Validity of this certificate can be verified at www.ukcertifications.co.uk/verify

Date of Certification	23 rd August 2018
1 st Surveillance Audit Due	22 nd August 2019
2 nd Surveillance Audit Due	22 nd August 2020
Certificate Expiry (subject to the company maintaining its system to the required standard)	22 nd August 2021



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Appendix-I

Appendix to Certificate no.:- CE-3569

Manufacturer : **Shagun Cares Inc.**

Product : **Orthopaedic Joint Replacement (Sterile & Non-Sterile)**



This certificate referred to above covers the following products like:

Product

S.No	Generic Name	Length	Dia
1	Thompson Hip prosthesis	N.A	37 mm to 55 mm
2	Austin moor Hip prosthesis	N.A	37 mm to 55 mm
3	Bipolar hip prosthesis (cementing and uncementing)	N.A	37 mm to 55 mm
4	Modular Bipolar hip prosthesis (cementing and uncementing)	N.A	37 mm to 55 mm
5	Hard portion of modular bipolar	N.A	37 mm to 55 mm
6	Hip Cup (cementing and uncementing)	N.A	37 mm to 65 mm
7	Modular femoral head	N.A	22mm to 32 mm
8	Muller stem (cementing and uncementing)	Small , Medium Large	N.A
9	Long stem (cementing and uncementing)	200,250,300 mm	N.A
10	Hip stem (cementing and uncementing)	OX , XL , 1, 2, 3, 4,	N.A
11	Tumour hip spacer (cementing and uncementing)	30 to 120 mm	30 mm
12	Tumour hip stem (cementing and uncementing)	100 to 200 mm	7to15 mm
13	Tumour hip resection Neck (cementing and uncementing)	Small , Medium Large	NA
14	Centralizers	N.A	10 to 14 mm
15	Cement stopper	N.A	40 mm
16	Liner	N.A	20 mm to 65 mm
17	Acetubular cup	N.A	37 mm to 65 mm
18	Custom Made Hip	N.A	N.A
19	Tumour Knee Spacer (cementing and uncementing)	Dia 30 mm length 30 to 120 mm	25 to-35 mm
20	Tumour knee stem (cementing and uncementing)	Dia 7to15 mm length 100 to 200 mm	7to30 mm
21	Hing Pin	Small, medium ,large	N.A
22	Condoyle tumour knee Distal femur	Small, medium ,large	N.A
23	Condoyle tumour knee proximal knee	Small, medium ,large	N.A
24	Tumour knee with total hip resection(cementing and uncementing)	Small, medium ,large	N.A
25	Revision Knee Femur	N.A	N.A
26	Revision knee tibia	N.A	N.A
27	Revision Knee Spacer	N.A	N.A
28	Knee Femur Part	N.A	N.A
29	Knee Tibia Part	N.A	N.A

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Certificate of Compliance

Appendix-II

Appendix to Certificate no.:- CE-3569

Manufacturer :

Shagun Cares Inc.

Product :

Orthopaedic Joint Replacement (Sterile & Non-Sterile)



This certificate referred to above covers the following products like:

Product

30	Spacer	N.A	N.A
31	Expandable knee	N.A	N.A
32	Custom made Knee	N.A	N.A
33	Shoulder Head	N.A	28 mm to 44 mm
34	Shoulder Neck	Small, Medium, Large	N.A
35	Shoulder Stem (cementing and uncementing)	85 to 150 mm	5 to 9 mm
36	Tumour Shoulder spacer (cementing and uncementing)	30 mm to 100 mm	18 to 25 mm
37	Tumour shoulder stem (cementing and uncementing)	85 to 150 mm	5 to 14 mm
38	Shoulder centralizer	Dia 10 to 13 mm	10 to 13 mm
39	Tumour Shoulder Neck	N.A	N.A
40	Reverse Shoulder	N.A	N.A
41	Expandable Shoulder	N.A	N.A
42	Custom Made Shoulder	N.A	N.A
43	Diaphysial spacer	20 to 120 mm	18 to 30 mm
44	Hing Pin for elbow prosthesis	Small , Medium Large	N.A
45	Humorous part for elbow prosthesis	2/3 mm , 3/4 mm ,5/6 mm	N.A
46	Ulna part for elbow	2/3 mm , 3/4 mm ,5/6 mm	N.A
47	Condoyle part for elbow prosthesis	Small , medium , large	N.A
48	Normal Elbow	N.A	N.A
49	Expandable Elbow	N.A	N.A
50	Custom Made Elbow	N.A	N.A
51	M.B.W Wrist Implants	Small, Medium, Large	N.A
52	P.I.P Finger Implants	Small, Medium, Large	N.A
53	ADAMCO M.C.P Implants	Small, Medium, Large	N.A
54	ACAMO C.M.C	Small, Medium, Large	N.A
55	MOLANA M.T.P Finger Implants	Small, Medium, Large	N.A
56	GLANOID PROSTHESIS	Small, Medium, Large	N.A
57	SCAPULA PROSTHESIS	Small, Medium, Large	N.A

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