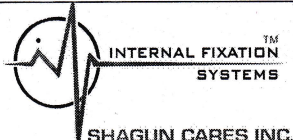
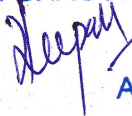


|                                                                                   |                           |                   |
|-----------------------------------------------------------------------------------|---------------------------|-------------------|
|  | Annex 08                  | Rev. 02           |
|                                                                                   | Declaration Of Conformity | Dated: 05.12.2017 |

UID No. :DOC\_Orthopeadic Implants-01

|                                                                                                                                          |                                                                                                                                                                                                                                                                                |
|------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Manufacture's Name:</b>                                                                                                               | Shagun Cares Inc.                                                                                                                                                                                                                                                              |
| <b>Manufacture's Address:</b>                                                                                                            | Manufacturing Address: C-27, D.S.I.D.C Industrial Complex, Rohtak Road, Nangloi, New Delhi 110041, India.<br>Ware House: Sector B-3, Plot No. C 22, Tronica City Industrial Area , Ghaziabad 201102, Uttar Pradesh, India                                                      |
| <b>Product Name:</b>                                                                                                                     | Orthopedic Implants (Refer Annex I – Product List) <ul style="list-style-type: none"> <li>- Bone Screws</li> <li>- Bone Plates</li> <li>- Locking Plates</li> <li>- Maxillofacial Implants,</li> <li>- Spinal Implants</li> <li>- Wires &amp; Pins</li> <li>- Nails</li> </ul> |
| <b>Brand Name</b>                                                                                                                        | Internal Fixation Systems<br>Ortho FIXOR<br>Shagun Cares                                                                                                                                                                                                                       |
| <b>Applicable Directive</b>                                                                                                              | Annex II – Full Quality Assurance of 93/42/EEC Medical Device Directives as amended 2007/47/EC excluding Section IV                                                                                                                                                            |
| <b>Classification</b>                                                                                                                    | IIb – (Rule 8 – Surgically invasive long term implantable devices)                                                                                                                                                                                                             |
| <b>Applicable Standards</b>                                                                                                              | Refer Annex-II for Applicable Standards                                                                                                                                                                                                                                        |
| <b>EU Rep</b>                                                                                                                            | Implant Manufacturing British Company Limited<br>30-34, New Bridge Street, London, U.K.<br>Contact Person: Ms. Nidhi<br>Tel: 020-74294100                                                                                                                                      |
| <b>Notified Body</b>                                                                                                                     | ITC (Notified Body No 1023)                                                                                                                                                                                                                                                    |
| <b>EC Certificate No.</b>                                                                                                                |                                                                                                                                                                                                                                                                                |
| <b>Valid Till</b>                                                                                                                        |                                                                                                                                                                                                                                                                                |
| The undersigned declares that the above-named products conform to the above Directives and Standards as applicable on the devices.       |                                                                                                                                                                                                                                                                                |
| Authorized Signatory<br><b>Name: Mr. Deepak Gupta</b><br><b>Director, Shagun Cares Inc.</b><br><b>Date: 6<sup>th</sup> December 2017</b> |                                                                                                                                                                                                                                                                                |

For SHAGUN CARES INC.



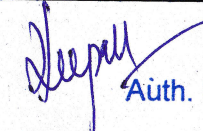
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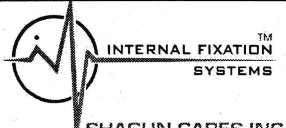
|                                                                                                                                             |              |                   |
|---------------------------------------------------------------------------------------------------------------------------------------------|--------------|-------------------|
|  <b>INTERNAL FIXATION<br/>SYSTEMS</b><br>SHAGUN CARES INC. | Annex-I      | Rev. 01           |
|                                                                                                                                             | Product List | Dated: 10.07.2017 |

**"ANNEX I – Product List"**

| DEVICE NAME                                    | DEVICE MODEL    | GMDN CODE | CLASS | MATERIAL | RULE | STERILE     | MD CODE |
|------------------------------------------------|-----------------|-----------|-------|----------|------|-------------|---------|
| <b>ORTHOPAEDIC BONE SCREWS</b>                 |                 |           |       |          |      |             |         |
| 1.5mm Cortical Screw                           | 6mm to 20mm     | 56642     | IIb   | S.S/Ti   | 8    | Non-Sterile | MD 202  |
| 2.0mm cortical screws                          | 6mm to 20mm     | 56642     | IIb   | S.S/Ti   | 8    | Non-Sterile | MD 202  |
| 2.7mm cortical screw                           | 6mm to 30mm     | 56642     | IIb   | S.S/Ti   | 8    | Non-Sterile | MD 202  |
| 3.5mm cortical screw                           | 10mm to 40mm    | 56642     | IIb   | S.S/Ti   | 8    | Non-Sterile | MD 202  |
| 3.5 mm Cancellous Screw                        | 10 to 40 mm     | 56642     | IIb   | S.S/Ti   | 8    | Non-Sterile | MD 202  |
| 4.0 mm Cancellous screw (short thread)         | 10 to 60 mm     | 56642     | IIb   | S.S/Ti   | 8    | Non-Sterile | MD 202  |
| 4.0 mm Cancellous screw (Full thread)          | 10mm to 60 mm   | 56642     | IIb   | S.S/Ti   | 8    | Non-Sterile | MD 202  |
| 4.0 mm Cannulated screw (full thread)          | 10mm to 60 mm   | 56642     | IIb   | S.S/Ti   | 8    | Non-Sterile | MD 202  |
| 4.0 mm Cannulated screw (short thread )        | 10 mm to 60 mm  | 56642     | IIb   | S.S/Ti   | 8    | Non-Sterile | MD 202  |
| 4.5 Cortical screw                             | 12mm to 120 mm  | 56642     | IIb   | S.S/Ti   | 8    | Non-Sterile | MD 202  |
| 4.5 mm Cortical screw (Self-Tapping )          | 12mm to 120 mm  | 56642     | IIb   | S.S/Ti   | 8    | Non-Sterile | MD 202  |
| 6.5 mm Cancellous screw (thread 16 mm )        | 12 mm to 100 mm | 56642     | IIb   | S.S/Ti   | 8    | Non-Sterile | MD 202  |
| 6.5 mm Cancellous screw (thread 32 mm )        | 35 mm to 100 mm | 56642     | IIb   | S.S/Ti   | 8    | Non-Sterile | MD 202  |
| 6.5 mm Cancellous screw (Full thread )         | 25 mm to 100 mm | 56642     | IIb   | S.S/Ti   | 8    | Non-Sterile | MD 202  |
| 7.0 mm & 6.5 mm Cannulated screw (16 thread)   | 50 mm to 110 mm | 56642     | IIb   | S.S/Ti   | 8    | Non-Sterile | MD 202  |
| 7.0 mm & 6.5 mm Cannulated screw (32 thread)   | 50 mm to 110 mm | 56642     | IIb   | S.S/Ti   | 8    | Non-Sterile | MD 202  |
| 7.0 mm & 6.5 mm Cannulated screw (Full thread) | 50 mm to 110 mm | 56642     | IIb   | S.S/Ti   | 8    | Non-Sterile | MD 202  |
| 4.5 mm Malleolar screw                         | 25mm to 80 mm   | 56642     | IIb   | S.S/Ti   | 8    | Non-Sterile | MD 202  |
| Compression screw                              | 36 mm           | 56642     | IIb   | S.S/Ti   | 8    | Non-Sterile | MD 202  |
| DHS/DCS Screw                                  | 50mm to 100 mm  | 56642     | IIb   | S.S/Ti   | 8    | Non-Sterile | MD 202  |
| Herbert Screw                                  | 12mm to 40 mm   | 56642     | IIb   | S.S/Ti   | 8    | Non-Sterile | MD 202  |
| 4.9 mm Locking bolt Self tapping               | 24 mm to 95 mm  | 56642     | IIb   | S.S/Ti   | 8    | Non-Sterile | MD 202  |
| 3.9 mm Locking bolt Self tapping               | 20 mm to 60 mm  | 56642     | IIb   | S.S/Ti   | 8    | Non-Sterile | MD 202  |
| Steffee Screw (4.5mm, 5.5mm, 6.5mm, 7.0mm)     | 28 mm to 44 mm  | 56642     | IIb   | S.S/Ti   | 8    | Non-Sterile | MD 202  |
| Screw 1.0 mm                                   | 6 mm to 20 mm   | 56642     | IIb   | S.S/Ti   | 8    | Non-Sterile | MD 202  |

For SHAGUN CARES INC.

  
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|                                                                                   |              |                   |
|-----------------------------------------------------------------------------------|--------------|-------------------|
|  | Annex-I      | Rev. 01           |
|                                                                                   | Product List | Dated: 10.07.2017 |

|                                                  |                 |       |     |        |   |             |        |
|--------------------------------------------------|-----------------|-------|-----|--------|---|-------------|--------|
| Screw 1.3 mm                                     | 6 mm to 20 mm   | 56642 | IIb | S.S/Ti | 8 | Non-Sterile | MD 202 |
| Screw 1.5 mm                                     | 6 mm to 20 mm   | 56642 | IIb | S.S/Ti | 8 | Non-Sterile | MD 202 |
| Screw 2.0 mm                                     | 6 mm to 20 mm   | 56642 | IIb | S.S/Ti | 8 | Non-Sterile | MD 202 |
| Screw 2.3 mm                                     | 6 mm to 20 mm   | 56642 | IIb | S.S/Ti | 8 | Non-Sterile | MD 202 |
| Screw 2.5 mm                                     | 6 mm to 40 mm   | 56642 | IIb | S.S/Ti | 8 | Non-Sterile | MD 202 |
| Screw 2.7 mm                                     | 6 mm to 40 mm   | 56642 | IIb | S.S/Ti | 8 | Non-Sterile | MD 202 |
| Emergency screw                                  | 6 mm to 40 mm   | 56642 | IIb | S.S/Ti | 8 | Non-Sterile | MD 202 |
| Locking thread Head screw 2.7 mm (self Tapping)  | 20 mm to 60 mm  | 56642 | IIb | S.S/Ti | 8 | Non-Sterile | MD 202 |
| Locking thread Head screw 3.5 mm (self Tapping)  | 10 mm to 95 mm  | 56642 | IIb | S.S/Ti | 8 | Non-Sterile | MD 202 |
| Locking thread Head screw 5.0 mm (self Tapping)  | 14 mm to 90 mm  | 56642 | IIb | S.S/Ti | 8 | Non-Sterile | MD 202 |
| Locking thread Head screw 2.7 mm (self Drilling) | 10 mm to 30 mm  | 56642 | IIb | S.S/Ti | 8 | Non-Sterile | MD 202 |
| Locking thread Head screw 3.5 mm (self Drilling) | 12 mm to 60 mm  | 56642 | IIb | S.S/Ti | 8 | Non-Sterile | MD 202 |
| Locking thread Head screw 5.0 mm (self Drilling) | 14 mm to 90 mm  | 56642 | IIb | S.S/Ti | 8 | Non-Sterile | MD 202 |
| Locking thread Head screw 5.0 mm Cannulated      | 25 mm to 145 mm | 56642 | IIb | S.S/Ti | 8 | Non-Sterile | MD 202 |
| Locking thread Head screw 2.0 mm (self Tapping)  | 10 mm to 30 mm  | 56642 | IIb | S.S/Ti | 8 | Non-Sterile | MD 202 |
| Locking thread Head screw 2.4 mm (self Tapping)  | 10 mm to 30 mm  | 56642 | IIb | S.S/Ti | 8 | Non-Sterile | MD 202 |
| Locking thread Head screw 2.0 mm (self Drilling) | 10 mm to 30 mm  | 56642 | IIb | S.S/Ti | 8 | Non-Sterile | MD 202 |
| Locking thread Head screw 2.4 mm (self Drilling) | 10 mm to 30 mm  | 56642 | IIb | S.S/Ti | 8 | Non-Sterile | MD 202 |
| Locking thread Head screw 6.5 mm (self Tapping)  | 30 mm to 120 mm | 56642 | IIb | S.S/Ti | 8 | Non-Sterile | MD 202 |
| Locking thread Head screw 7.0 mm (self Tapping)  | 30 mm to 120 mm | 56642 | IIb | S.S/Ti | 8 | Non-Sterile | MD 202 |
| Locking thread Head screw 7.3 mm (self Tapping)  | 30 mm to 120 mm | 56642 | IIb | S.S/Ti | 8 | Non-Sterile | MD 202 |
| Locking thread Head screw 7.3 Cannulated         | 30 mm to 120 mm | 56642 | IIb | S.S/Ti | 8 | Non-Sterile | MD 202 |
| Interference screw                               | 30 mm to 120 mm | 56642 | IIb | S.S/Ti | 8 | Non-Sterile | MD 202 |
| ACL screw                                        | 30 mm to 120 mm | 56642 | IIb | S.S/Ti | 8 | Non-Sterile | MD 202 |
| ACL Pin                                          | 30 mm to 120 mm | 56642 | IIb | S.S/Ti | 8 | Non-Sterile | MD 202 |
|                                                  |                 |       |     |        |   |             |        |
| 4.5 mm Cortical cannulated screws Short thread   | 12mm to 42 mm   | 56642 | IIb | S.S/Ti | 8 | Non-Sterile | MD 202 |
| 4.5 mm Cortical cannulated screws full thread    | 12mm to 42 mm   | 56642 | IIb | S.S/Ti | 8 | Non-Sterile | MD 202 |
| 3.5mm cortical screw ( Self tapping )            | 10mm to 50mm    | 56642 | IIb | S.S/Ti | 8 | Non-Sterile | MD 202 |
| 7.0 mm Cancellous cannulated screw (full thread) | 12 mm to 100 mm | 56642 | IIb | S.S/Ti | 8 | Non-Sterile | MD 202 |
| Locking Bolt 6.5 mm                              | 30 mm to 100 mm | 56642 | IIb | S.S/Ti | 8 | Non-Sterile | MD 202 |

FOR SHAGUN CARES INC.

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