

Certificate of Compliance

CE

We hereby declare that the technical files of all the items in each product group of complied with the requirements of the Council Directive on Medical Devices 93/42/EEC as Amended 2007/47/EC.

Certificate No.: CE-1888

Manufacturer

Name : SIGMA SURGICAL PRIVATE LIMITED

Address : Survey No. 1636/1, Opp. Bharat Petroleum, Indore Highway,
Village - Kuha, Taluka - Daskroi, Ahmedabad - 382433,
Gujarat, India

Product : Surgical Equipments
(More Details as per Appendix I-XVIII)

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 the Council Directive on Medical Devices 93/42/EEC as Amended 2007/47/EC.

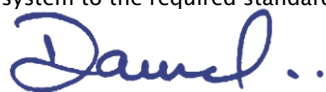
This certificate is issued under the following conditions:

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 changed.
3. The certificate validity is conditioned by positive results or surveillance audits.

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.org.uk/verify

Date of initial registration	12 th November 2021
Date of this certificate	11 th November 2023
Certificate Expiry	11 th November 2024
Recertification Due (subject to the company maintaining its system to the required standard)	11 th November 2024



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Certificate of Compliance

Appendix-I

Appendix to Certificate no.:- **CE-1888**

Manufacturer

:- **SIGMA SURGICAL PRIVATE LIMITED**

Address

:- Survey No. 1636/1, Opp. Bharat Petroleum, Indore
Highway, Village - Kuha, Taluka - Daskroi,
Ahmedabad - 382433, Gujarat, India



This certificate referred to above covers the following products like:

Products:-

Product Code	Name of Product	Product Code	Name of Product
1. INSTRUMENT SET FOR CLASSIC INTERLOCKING NAIL FOR TIBIAL BONE			
J0010.001	Bone AWL with T Handle	J0090.001	Hammer
J0020.001	Conical Bolt	J0100.001	Hammering Bolt
J0030.001	Depth Guage	J0110.001	Impactor Extractor
J0040.001	Distal Device	J0120.001	Protection Sleeve, 10.0 mm x 8.0 mm (Short)
J0050.001	Distal device bolt	J0130.001	Main Zig
J2200.300	Drill Bit, 4.0 mm x 300 mm	J0140.001	Screw Driver, 4.9 mm, Hexagonal
J2180.250	Drill Bit, 3.2 mm x 250 mm	J0150.001	Spanner
J0060.001	Drill Sleeve, 8.0 mm x 4.0 mm	J0160.001	Tefflon Sleeve
J0060.002	Drill Sleeve, 8.0 mm x 3.2 mm	J0170.001	Tissue Protector
J0080.001	Guide Wire Pusher	J0180.001	Trocar
J1900.115	Guide Wire, 2.5 mm x 115 cm(Simple)	J0220.001	Implant Tray
J2010.115	Guide Wire, 2.5 mm x 115 cm(Bullet Tips)	J0190.001	Instrument Box
J0200.001	COMPLETE INSTRUMENT SET FOR CLASSIC INTERLOCKING NAIL FOR TIBIAL BONE		
2. INSTRUMENT SET FOR CLASSIC INTERLOCKING NAIL FOR FEMORAL BONE			
J0010.001	Bone AWL with T Handle	J0110.001	Impactor Extractor
J0020.002	Conical Bolt	J0120.001	Protection Sleeve, 10.0 mm x 8.0 mm (Short)
J0030.001	Depth Guage	J0130.002	Main Zig
J0040.002	Distal Device	J0140.001	Screw Driver, 4.9 mm, Hexagonal
J0050.001	Distal device bolt	J0150.001	Spanner
J2200.300	Drill Bit, 4.0 mm x 300 mm	J0160.001	Tefflon Sleeve
J0060.001	Drill Sleeve, 8.0 mm x 4.0 mm	J0170.001	Tissue Protector
J0080.001	Guide Wire Pusher	J0180.001	Trocar
J1900.115	Guide Wire, 2.5 mm x 115 cm(Simple)	J0220.001	Implant Tray
J2010.115	Guide Wire, 2.5 mm x 115 cm(Bullet Tips)	J0190.001	Instrument Box
J0090.001	Hammer	J0200.002	COMPLETE INSTRUMENT SET FOR CLASSIC INTERLOCKING NAIL FOR FEMORAL BONE
J0100.001	"Hammering Bolt"		

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Appendix to Certificate no.:- CE-1888
Manufacturer :- SIGMA SURGICAL PRIVATE LIMITED
Address :- Survey No. 1636/1, Opp. Bharat Petroleum, Indore
Highway, Village - Kuha, Taluka - Daskroi,
Ahmedabad - 382433, Gujarat, India



This certificate referred to above covers the following products like:

Products: -

3. INSTRUMENT SET FOR RECON INTERLOCKING NAIL			
J0010.001	Bone AWL with T Handle	J0100.001	Hammering Bolt
J0300.001	Bone AWL, Cannulated, 13.5 mm	J0110.001	Impactor Extractor
J0230.001	Bone Drill, 6.3 mm	J0120.001	Protection Sleeve, 10.0 mm x 8.0 mm (Short)
J0240.001	Tap, 6.3 mm	J0120.002	Protection Sleeve, 10.0 mm x 8.0 mm (Long)
J0020.002	Conical Bolt	J0130.002	Main Zig
J0030.001	Depth Guage	J0270.001	Proximal Device
J0040.002	Distal Device	J0140.001	Screw Driver, 4.9 mm, Hexagonal
J0050.001	Distal device bolt	J0140.002	Screw Driver, Cannulated, 5.0 mm, Hexagonal
J2200.300	Drill Bit, 4.0 mm x 300 mm	J0150.001	Spanner
J0060.001	Drill Sleeve, 8.0 mm x 4.0 mm	J0160.001	Teflon Sleeve
J0080.001	Guide Wire Pusher	J0170.001	Tissue Protector
J1900.115	Guide Wire, 2.5 mm x 115 cm(Simple)	J0290.001	Tissue Protection Sleeve
J2010.115	Guide Wire, 2.5 mm x 115 cm(Bullet Tips)	J0180.002	Trocar (Long)
J0250.001	Guide Wire Sleeve, 8.0 mm x 2.5 mm	J0190.002	Instrument Box
J1980.014	Guide Wire Trocar Point, 2.5mm x 14"(Threaded)	J0200.003	COMPLETE INSTRUMENT SET FOR RECON INTERLOCKING NAIL
J1970.014	Guide Wire Trocar Point, 2.5 mm x 14" (Simple)	J0210.001	Implant Box (For Recon)
J0090.001	Hammer		
4. INSTRUMENT SET FOR ANTEGRADE INTERLOCKING NAIL FOR FEMORAL BONE			
J0010.001	Bone AWL with T Handle	J0120.001	Protection Sleeve, 10.0 mm x 8.0 mm (Short)
J0300.001	Bone AWL, Cannulated, 13.5 mm	J0120.002	Protection Sleeve, 10.0 mm x 8.0 mm (Long)
J0230.001	Bone Drill, 6.3 mm	J0120.011	Protection Sleeve, 12.0 mm x 8.0 mm (Long)
J0240.001	Tap, 6.3 mm	J0130.002	Main Zig
J0020.002	Conical Bolt	J0270.002	Proximal Device 130°
J0030.001	Depth Guage	J0270.003	Proximal Device 135°
J0050.001	Distal device bolt	J0280.001	Quick Coupling " T " Handle
J2200.300	Drill Bit, 4.0 mm x 300 mm	J0140.001	Screw Driver, 4.9 mm, Hexagonal
J0060.001	Drill Sleeve, 8.0 mm x 4.0 mm	J0140.002	Screw Driver, Cannulated, 5.0 mm, Hexagonal
J0080.001	Guide Wire Pusher	J0150.001	Spanner
J1900.115	Guide Wire, 2.5 mm x 115 cm(Simple)	J0160.001	Teflon Sleeve
J2010.115	Guide Wire, 2.5 mm x 115 cm(Bullet Tips)	J0170.001	Tissue Protector
J0250.001	Guide Wire Sleeve, 8.0 mm x 2.5 mm	J0290.001	Tissue Protection Sleeve
J1980.014	Guide Wire Trocar Point, 2.5mm x 14"(Threaded)	J0180.002	Trocar (Long)
J1970.014	Guide Wire Trocar Point, 2.5 mm x 14" (Simple)	J0190.002	Instrument Box
J0090.001	Hammer	J0200.004	COMPLETE INSTRUMENT SET FOR ANTEGRADE INTERLOCKING NAIL FOR FEMORAL BONE
J0100.001	Hammering Bolt	J0210.001	Implant Box
J0110.001	Impactor Extractor		

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Certificate of Compliance
 71-72, Shelton Street, Covent Garden, London, WC2H 9JQ, United Kingdom
 www.ukcertifications.org.uk, email:- info@ukcertifications.org.uk
 Company No. 11847851

Appendix-III

Appendix to Certificate no.:- CE-1888
Manufacturer :- SIGMA SURGICAL PRIVATE LIMITED
Address :- Survey No. 1636/1, Opp. Bharat Petroleum, Indore
Highway, Village - Kuha, Taluka - Daskroi,
Ahmedabad - 382433, Gujarat, India



This certificate referred to above covers the following products like:

Products:-

5. INSTRUMENT SET FOR PROXIMAL INTERLOCKING NAIL FOR FEMORAL BONE			
J0010.001	Bone AWL with T Handle	J0090.001	Hammer
J0300.002	Bone AWL, Cannulated, 14.5 mm	J0100.001	Hammering Bolt
J0230.001	Bone Drill, 6.3 mm	J0110.001	Impactor Extractor
J0230.002	Bone drill, 8.0 mm	J0120.001	Protection Sleeve, 10.0 mm x 8.0 mm (Short)
J0240.001	Tap, 6.3 mm	J0120.002	Protection Sleeve, 10.0 mm x 8.0 mm (Long)
J0240.002	Tap, 8.0 mm	J0120.012	Protection Sleeve, 12.0 mm x 10.0 mm (Long)
J0020.002	Conical Bolt	J0130.002	Main Zig
J0030.001	Depth Guage	J0270.002	Proximal Device 130°
J0050.001	Distal device bolt	J0270.003	Proximal Device 135°
J0060.001	Drill Sleeve, 8.0 mm x 4.0 mm	J0280.001	Quick Coupling " T " Handle
J2200.300	Drill Bit, 4.0 mm x 300 mm	J0140.001	Screw Driver, 4.9 mm, Hexagonal
J0080.001	Guide Wire Pusher	J0140.002	Screw Driver, Cannulated, 5.0 mm, Hexagonal
J1900.115	Guide Wire, 2.5 mm x 115 cm(Simple)	J0150.001	Spanner
J2010.115	Guide Wire, 2.5 mm x 115 cm(Bullet Tips)	J0160.001	Teflon Sleeve
J0250.002	Guide Wire Sleeve, 10.0 mm x 3.0 mm	J0170.001	Tissue Protector
J0250.001	Guide Wire Sleeve, 8.0 mm x 2.5 mm	J0290.001	Tissue Protection Sleeve
J1980.014	Guide Wire Trocar Point, 2.5 mm x 14" (Threaded)	J0180.002	Trocar (Long)
J1970.014	Guide Wire Trocar Point, 2.5 mm x 14" (Simple)	J0190.002	Instrument Box
J1990.014	Guide Wire Trocar Point, 3.0 mm x 14" (Simple)	J0200.005	COMPLETE INSTRUMENT SET FOR PROXIMAL INTERLOCKING NAIL FOR FEMORAL BONE
J2000.014	Guide Wire Trocar Point, 3.0 mm x 14" (Threaded)	J0210.001	Implant Box
6. INSTRUMENT SET FOR HYPER INTERLOCKING NAIL FOR TIBIAL BONE			
J0010.001	Bone AWL with T Handle	J0100.002	Hammering Bolt
J0020.003	Conical Bolt	J0110.002	Impactor Extractor
J0030.001	Depth Guage	J0120.001	Protection Sleeve, 10.0 mm x 8.0 mm (Short)
J0040.003	Distal Device	J0130.003	Main Zig
J0050.002	Distal device bolt	J0320.001	Oblique Proximal Locking Device
J2200.300	Drill Bit, 4.0 mm x 300 mm	J0140.001	Screw Driver, 4.9 mm, Hexagonal
J2180.250	Drill Bit, 3.2 mm x 250 mm	J0390.001	Allen Key
J0060.001	Drill Sleeve, 8.0 mm x 4.0 mm	J0160.001	Teflon Sleeve
J0060.002	Drill Sleeve, 8.0 mm x 3.2 mm	J0170.001	Tissue Protector
J0080.001	Guide Wire Pusher	J0180.001	Trocar
J1900.115	Guide Wire, 2.5 mm x 115 cm(Simple)	J0220.001	Implant Tray
J2010.115	Guide Wire, 2.5 mm x 115 cm(Bullet Tips)	J0190.001	Instrument Box
J0090.001	Hammer	J0200.006	COMPLETE INSTRUMENT SET FOR HYPER INTERLOCKING NAIL FOR TIBIAL BONE

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Certificate of Compliance

Appendix-IV

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 Website:- www.ukcertifications.org.uk, Email:- info@ukcertifications.org.uk
 Company No. 11847851

Appendix to Certificate no.:- CE-1888

Manufacturer

Address

:- SIGMA SURGICAL PRIVATE LIMITED

**:- Survey No. 1636/1, Opp. Bharat Petroleum, Indore
Highway, Village - Kuha, Taluka - Daskroi,
Ahmedabad - 382433, Gujarat, India**



This certificate referred to above covers the following products like:

Products: -

7. INSTRUMENT SET FOR HYPER INTERLOCKING NAIL FOR FEMORAL BONE			
J0010.001	Bone AWL with T Handle	J0110.002	Impactor Extractor
J0020.003	Conical Bolt	J0120.001	Protection Sleeve, 10.0 mm x 8.0 mm (Short)
J0030.001	Depth Gauge	J0130.003	Main Zig
J0040.004	Distal Device	J0140.001	Screw Driver, 4.9 mm, Hexagonal
J0050.002	Distal device bolt	J0390.001	Allen Key
J2200.300	Drill Bit, 4.0 mm x 300 mm	J0160.001	Tefflon Sleeve
J0060.001	Drill Sleeve, 8.0 mm x 4.0 mm	J0170.001	Tissue Protector
J0080.001	Guide Wire Pusher	J0180.001	Trocar
J1900.115	Guide Wire, 2.5 mm x 115 cm(Simple)	J0220.001	Implant Tray
J2010.115	Guide Wire, 2.5 mm x 115 cm(Bullet Tips)	J0190.001	Instrument Box
J0090.001	Hammer	J0200.007	COMPLETE INSTRUMENT SET FOR HYPER INTERLOCKING NAIL FOR FEMORAL BONE
J0100.002	Hammering Bolt		
8. INSTRUMENT SET FOR CLASSIC INTERLOCKING NAIL FOR HUMERUS BONE			
J0010.002	Bone AWL	J0090.001	Hammer
J0330.001	Compression Device	J0100.003	Hammering Bolt
J0340.001	Compression Screw	J0110.003	Impactor Extractor
J0020.004	Conical Bolt	J0120.010	Protection Sleeve, 8.0 mm x 6.0 mm
J0030.002	Depth Gauge	J0130.004	Main Zig
J0050.002	Distal device bolt	J0140.003	Screw Driver, 3.4mm, Hexagonal
J0040.005	Distal Device	J0390.001	Allen Key
J2150.250	Drill Bit, 2.7 mm x 250 mm	J0180.003	Trocar
J0060.003	Drill Sleeve, 2.7mm x 6.0 mm	J0220.002	Implant Tray
J0360.001	Extractor Screw	J0190.003	Instrument Box
J2040.020	Guide Wire, 1.8 mm X 20" (Simple)	J0200.008	COMPLETE INSTRUMENT SET FOR CLASSIC INTERLOCKING NAIL FOR HUMERUS BONE
9. INSTRUMENT SET FOR DISTAL INTERLOCKING NAIL FOR FEMORAL BONE			
J0010.001	Bone AWL with T Handle	J0100.001	Hammering Bolt
J0020.001	Conical Bolt	J0110.001	Impactor Extractor
J0030.001	Depth Gauge	J0120.001	Protection Sleeve, 10.0 mm x 8.0 mm (Short)
J0040.006	Distal Device	J0130.001	Main Zig
J0050.001	Distal device bolt	J0140.001	Screw Driver, 4.9 mm, Hexagonal
J2200.300	Drill Bit, 4.0 mm x 300 mm	J0150.001	Spanner
J2230.300	Drill Bit, 5.0 mm x 300 mm	J0160.001	Tefflon Sleeve
J0060.001	Drill Sleeve, 8.0 mm x 4.0 mm	J0170.001	Tissue Protector
J0060.004	Drill Sleeve, 8.0 mm x 5.0 mm	J0180.001	Trocar
J0080.001	Guide Wire Pusher	J0220.001	Implant Tray
J1900.115	Guide Wire, 2.5 mm x 115 cm(Simple)	J0190.001	Instrument Box
J2010.115	Guide Wire, 2.5 mm x 115 cm(Bullet Tips)	J0200.009	COMPLETE INSTRUMENT SET FOR DISTAL INTERLOCKING NAIL FOR FEMORAL BONE
J0090.001	Hammer		

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Manufacturer

SIGMA SURGICAL PRIVATE LIMITED

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Appendix-V

Address

:- Survey No. 1636/1, Opp. Bharat Petroleum, Indore
Highway, Village - Kuha, Taluka - Daskroi,
Ahmedabad - 382433, Gujarat, India



This certificate referred to above covers the following products like:

Products: -

10. INSTRUMENT SET FOR HYPER PROXIMAL INTERLOCKING NAIL FOR FEMORAL BONE			
J0010.001	Bone AWL with T Handle	J0130.005	Main Zig
J0390.002	Allen Key	J0120.003	Protection Sleeve 11.0 mm x 8.0 mm
J0400.001	Cannulated Instrument Cleaner, 3.0 mm	J0460.002	Proximal Entry reamer, 15.5 mm
J0090.002	Combined Hammer	J0460.005	Proximal Entry reamer, 16.5 mm
J0340.002	Compression Screw	J0120.004	Protection Sleeve For PFN Blade 16.0 mm x 11.0 mm
J0020.005	Conical Bolt	J0290.002	Tissue Protection Sleeve 15.5 mm
J0410.001	Connecting Screw	J0290.005	Tissue Protection Sleeve 16.5 mm
J0420.001	Connector For Main Zig	J0280.002	Quick Coupling " T " Handle
J0430.001	Cross Hole Device	J0520.001	Reamer 10.0 mm For PFN Blade
J0030.003	Depth Gauge	J0140.001	Screw Driver, 4.9 mm, Hexagonal
J0270.007	Proximal Device 130°	J0140.004	Screw Driver Hexagonal with Spherical Head
J0440.001	Direct Measuring Device For Guide Wire	J0150.003	Spanner 11 mm
J0040.007	Distal Device	J0170.001	Tissue Protector
J2200.325	Drill Bit, 4.0 mm x 325 mm	J0180.004	Trocar 3.2 mm
J2180.300	Drill Bit, 3.2 mm x 300 mm	J0180.012	Trocar, 8.0 mm
J0060.005	Drill Sleeve, 8.0 mm x 3.2 mm	J0530.001	Wire Guide
J0060.006	Drill Sleeve, 8.0 mm x 4.0 mm	J0540.001	Screw Introducer
J0450.001	End Cap Box Spanner with Capture	J0140.005	Screw Driver For Connecting Screw
J0450.002	End Cap Box Spanner with fixed Capture	J0930.001	Screw Compression Device
J0460.001	Entry Reamer 10 mm For PFN Blade	J0550.001	Drill Bit Stopper, 4.0 mm
J0470.001	Extractor Rod For PFN Blade	J0550.002	Drill Bit Stopper, 3.2 mm
J0080.002	Guide Wire Pusher	J0210.013	Implant Box (For Hyper PFN Screw)
J1900.115	Guide Wire, 2.5 mm x 115 cm(Simple)	J0190.004	Instrument Box
J2010.115	Guide Wire, 2.5 mm x 115 cm (Bullet Tips)	J0200.010	COMPLETE INSTRUMENT SET FOR HYPER PROXIMAL INTERLOCKING NAIL FOR FEMORAL BONE
J0250.003	Guide wire Sleeve 11.0 mm x 3.2 mm	J0210.002	Implant Box
J0250.004	Guide Wire Sleeve 15.5 mm x 3.2 mm	J0210.003	Implant Box
J0250.008	Guide Wire Sleeve 16.5 mm x 3.2 mm	J0070.001	Drill Sleeve, 8.0 mm x 3.2 mm with T handle
J2050.400	Guide Wire, 3.2 mm x 400 mm (Threaded)	J0070.002	Drill Sleeve, 8.0 mm x 4.0 mm with T handle
J0480.001	Hammer Guide	J0560.001	Attachment For Hyper PFN Reamer
J0490.001	Impactor For PFN Blade	J0560.002	Attachment For Flexible Reamer
J0150.002	Spanner For PFN Blade	J2180.170	Drill Bit, 3.2 mm x 170 mm
J0470.002	Extractor Rod For Lag Screw	J2200.170	Drill Bit, 4.0 mm x 170 mm
J0440.002	Direct Measuring Device For Cross Hole	J0570.001	Rular Scale
11. INSTRUMENT SET FOR HYPER DISTAL INTERLOCKING NAIL FOR FEMORAL BONE			
J0270.008	Aiming Arm For Spiral Blade Locking	J2050.400	Guide Wire, 3.2 mm x 400 mm (Threaded)
J0040.008	Aiming Arm For Standard Locking	J0080.001	Guide Wire Pusher
J0040.009	Distal Device	J0250.005	Guide Wire Sleeve, 3.2 mm, Pink
J0010.003	Bone AWL	J0480.001	Hammer Guide
J0090.002	Combined Hammer	J0100.004	Hammering Bolt



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Appendix-VI

Appendix to Certificate no.:- CE-1888

Manufacturer

:- SIGMA SURGICAL PRIVATE LIMITED

Address

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Highway, Village - Kuha, Taluka - Daskroi,
Ahmedabad - 382433, Gujarat, India
Website:- www.ukcertifications.org.uk, email:- info@ukcertifications.org.uk
Company No. 11847851

Ahmedabad - 382433, Gujarat, India



This certificate referred to above covers the following products like:

Products: -

J0020.006	Conical Bolt	J0130.006	Main Zig
J0020.008	Conical Bolt V2	J0290.003	Tissue Protection Sleeve For entry reamer Dia. 13.00 mm
J0580.001	Connecting Screw For Spiral Blade	J0120.005	Protection Sleeve For 6.0 mm Screw-GREEN
J0410.001	Connecting Screw	J0120.013	Protection Sleeve For 4.9 mm Screw
J0030.001	Depth Gauge	J0280.002	Quick Coupling " T " Handle
J2200.300	Drill Bit, 4.0 mm x 300 mm	J0120.006	Protection Sleeve For Spiral blade Reamer Pink
J2230.300	Drill Bit, 5.0 mm x 300 mm	J0140.001	Screw Driver, 4.9 mm, Hexagonal
J0070.003	Drill Sleeve, 10.0 mm x 8.0 mm, With Handle	J0630.001	Spiral Blade Inserter
J0060.007	Drill Sleeve, 8.0 mm x 4.0 mm, Short	J0640.001	Tommy Bar
J0600.001	Drill Sleeve For 6 mm Screw- Green	J0180.006	Trocar, 5.0 mm-Green
J0600.002	Drill Sleeve For 4.0 mm drill	J0180.005	Trocar
J0610.001	Drill Sleeve For guide pin 3.2 mm entry reamer	J0180.011	Trocar, 4.0 mm
J0440.003	Direct Measuring Device For 3.2 mm Guide wire	J0190.005	Instrument Box
J0470.003	Extractor Rod For Blade	J0200.011	COMPLETE INSTRUMENT SET FOR HYPER DISTAL INTERLOCKING NAIL FOR FEMORAL BONE
J0360.002	Extraction Screw For Hyper DFN Nail Removal	J0210.004	Implant Box
J0360.003	Extraction Screw For Spiral Blade Remover	J0420.001	Connector For Main Zig
J0460.003	Entry Reamer Dia. 13.0 mm For Hyper DFN nail & Spiral Blade		
12. INSTRUMENT SET FOR PROXIMAL INTERLOCKING NAIL FOR FEMORAL BONE, MARC 1(PFN(M))			
J0010.001	Bone AWL with T Handle	J0270.004	Proximal Device 125°
J0400.002	Cannulated Instrument Cleaner, 2.5 mm	J0270.005	Proximal Device 130°
J0520.002	Reamer 11.0 mm	J0270.006	Proximal Device 135°
J0090.002	Combined Hammer	J0460.004	Proximal Entry reamer, Dia. 17.5 mm
J0020.007	Conical Bolt	J0280.002	Quick Coupling " T " Handle
J0030.001	Depth Gauge	J0520.003	Reamer 6.5 mm For Lag Screw Cannulated
J0440.004	Direct Measuring Device	J0570.001	Ruler
J2200.300	Drill Bit, 4.0 mm x 300 mm	J0830.002	Wrench For PFN Reamer 11 mm Neck Screw
J0650.001	Drill Sleeve, Dia. 12.0 mm x 2.8 mm - Pink	J0140.006	Screw Driver For 6.50 mm Cannulated screw
J0660.001	Drill Sleeve, Dia. 17.0 mm x 2.8 mm- Yellow	J0140.004	Screw Driver Hexagonal with Spherical Head
J0670.001	Drill Sleeve, Dia. 8.0 mm x 2.8 mm - Blue	J0140.001	Screw Driver, 4.9 mm, Hexagonal
J0060.008	Drill Sleeve, Dia. 8.0 mm x 4.0 mm	J0580.002	Connecting Screw For 11 mm Neck Screw
J0080.001	Guide Wire Pusher	J0170.001	Tissue Protector
J1900.115	Guide Wire, 2.5 mm x 115 cm(Simple)	J0640.001	Tommy Bar
J2010.115	Guide Wire, 2.5 mm x 115 cm (Bullet Tips)	J0180.007	Trocar, Dia. 2.8 mm - Blue
J2060.350	Guide Wire, Dia. 2.8 mm x 350 mm(Threaded)	J0180.008	Trocar, Dia. 2.8 mm - Pink
J0480.001	Hammer Guide	J0180.009	Trocar, Dia. 2.8 mm - Yellow
J0100.005	Hammering Bolt	J0180.010	Trocar, Dia. 4.0 mm



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Certificate of Compliance

Appendix-VII

Appendix to Certificate no.:- **CE-1888**

Manufacturer :- **SIGMA SURGICAL PRIVATE LIMITED**

Address :- **Survey No. 1636/1, Opp. Bharat Petroleum, Indore**

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 Website:- www.ukcertifications.org.uk, email:- info@ukcertifications.org.uk
 Company No. 11847851



This certificate referred to above covers the following products like:

Products: -

J0130.007	Main Zig	J0530.001	Wire Guide
J0120.007	Protection Sleeve, Dia. 10.0 mm x 8.0 mm - Blue	J0220.010	Implant Tray
J0120.008	Protection Sleeve, Dia. 11.0 mm x 8.0 mm	J0190.006	Instrument Box
J0120.009	Protection Sleeve, Dia. 14.0 mm x 12.0 mm - Pink	J0200.012	COMPLETE INSTRUMENT SET FOR PROXIMAL INTERLOCKING NAIL FOR FEMORAL BONE, MARC 1
J0290.004	Tissue Protection Sleeve, Dia. 20.0 mm x 17.5 mm		
13. INSTRUMENT SET FOR ELASTIC NAIL			
J0310.001	Bone AWL, Straight	J0090.003	Hammer Slotted
J0720.001	Bender 1	J0260.001	Medullary Neddle Holding Forceps
J0720.002	Bender 2	J0700.001	Nail Inserter
J0690.001	Cutter for use titanium Elastic nail	J0710.001	Rod For F Tool
J0730.005	Double Drill Guide Sleeve 3.2 mm / 4.5 mm	J0490.002	Impactor 2
J2150.150	Drill Bit, 2.7 mm x 150 mm	J0490.003	Impactor 1
J2180.200	Drill Bit, 3.2 mm x 200 mm	J0220.011	Implant Tray
J2220.200	Drill Bit, 4.5 mm x 200 mm	J0190.007	Instrument Box
J0480.002	Hammer Guide	J0200.013	COMPLETE INSTRUMENT SET FOR ELASTIC NAIL
14. INSTRUMENT SET FOR DISTAL FEMORAL COMPRESSION PLATE /FEMORAL HEAD COMPRESSION PLATE			
J0750.001	Angle Guide Adjustable	J1950.230	Guide Wire, 2.5 mm x 230 mm (Threaded)
J0750.002	Angle Guide Fix For DCS 95°	J0490.004	Impactor
J0750.003	Angle Guide Fix For DHS 130°	J0140.007	Screw Driver, 3.5 mm, Hexagonal
J0750.004	Angle Guide Fix For DHS 135°	J0280.001	Quick Coupling " T " Handle
J0780.001	Centering Sleeve - Long	J0280.003	T handle With Quick Coupling For Drill/ Tap
J0780.002	Centering Sleeve - Short	J0240.003	Tap For DHS/DCS
J0790.001	Coupling Screw - Short	J0240.004	Tap, 4.5 mm
J0030.005	Depth Gauge, 4.5 mm	J0810.001	Triple Reamer For Distal Femoral Compression Plate
J0440.005	Direct Measuring Device for DHS Screw	J0810.002	Triple Reamer For Femoral Head Compression Plate
J2340.150	Drill Bit with Quick Coupling, 3.2 mm x 150 mm	J0830.001	Wrench
J0800.001	Guide Shaft	J0190.008	Instrument Box
J1900.230	Guide Wire, 2.5 mm x 230 mm (Simple)	J0200.014	COMPLETE INSTRUMENT SET FOR DISTAL FEMORAL COMPRESSION PLATE /FEMORAL HEAD COMPRESSION PLATE
15. INSTRUMENT SET FOR TWIN LOCK-BCP DISTAL FEMORAL COMPRESSION PLATE /FEMORAL HEAD COMPRESSION PLATE			
J0750.001	Angle Guide Adjustable	J1950.230	Guide Wire, 2.5 mm x 230 mm (Threaded)
J0750.002	Angle Guide Fix For DCS 95°	J0490.004	Impactor
J0750.003	Angle Guide Fix For DHS 130°	J2520.150	K Wire, Simple, 2.0 mm x 150 mm
J0750.004	Angle Guide Fix For DHS 135°	J0140.007	Screw Driver, 3.5 mm, Hexagonal

Daniel..



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Certificate of Compliance

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Appendix-VIII

Appendix to Certificate no.- CE-1888

Manufacturer

:- SIGMA SURGICAL PRIVATE LIMITED

Address

:- Survey No. 1636/1, Opp. Bharat Petroleum, Indore Highway, Village - Kuha, Taluka - Daskroi, Ahmedabad - 382433, Gujarat, India



This certificate referred to above covers the following products like:

Products: -

J0780.001	Centering Sleeve - Long	J0140.008	Screw Driver, Cannulated, 3.5 mm, Hexagonal
J0780.002	Centering Sleeve - Short	J0840.002	Screw Driver Shaft, 3.5 mm, Hexagonal
J0790.001	Coupling Screw - Short	J0280.001	Quick Coupling " T " Handle
J0030.005	Depth Gauge, 4.5 mm	J0280.003	T handle With Quick Coupling For Drill/ Tap
J0440.006	Direct Measuring Device For DHS Screw	J0240.003	Tap For DHS/DCS
J0730.005	Double Drill Guide Sleeve 3.2 mm / 4.5 mm	J0240.004	Tap, 4.5 mm
J2340.150	Drill Bit with Quick Coupling, 3.2 mm x 150 mm	J0240.006	Tap, Cannulated, 6.5 mm
J2370.225	Drill Bit with Quick Coupling, 4.3 mm x 225 mm	J0370.002	Torque Limiting Screw Driver 5.0 mm
J2450.200	Drill bit, 4.5 mm x 200 mm, Cannulated	J0810.001	Triple Reamer For Distal Femoral Compression Plate
J0740.006	Drill Sleeve For Twin Lock-BCP, 4.3 mm	J0810.002	Triple Reamer For Femoral Head Compression Plate
J0800.001	Guide Shaft	J0830.001	Wrench
J1890.230	Guide Wire, 2.0 mm x 230 mm (Simple)	J0190.009	Instrument Box
J1940.230	Guide Wire, 2.0 mm x 230 mm (Threaded)	J0200.015	COMPLETE INSTRUMENT SET FOR TWIN LOCK-BCP DISTAL FEMORAL COMPRESSION PLATE /FEMORAL HEAD COMPRESSION PLATE
J1900.230	Guide Wire, 2.5 mm x 230 mm (Simple)		
16. INSTRUMENT SET FOR 3.5 MM LOCKING SYSTEM			
J0030.004	Depth Gauge, 2.7/3.5 mm	J0140.010	Screw Driver, Cannulated, 3.7 mm
J0440.007	Direct Measuring Device	J0840.003	Screw Driver Shaft, Cannulated, 3.7 mm, Hexagonal
J0730.004	Double Drill Guide Sleeve 2.5 mm / 3.5 mm	J0880.002	Screw Holding Device, 3.5 mm, Hexagonal
J2300.150	Drill Bit with Quick Coupling, 2.5 mm x 150 mm	J0280.003	T handle With Quick Coupling For Drill/ Tap
J2300.200	Drill Bit with Quick Coupling, 2.5 mm x 200 mm	J0900.001	T Handle For Twin Lock-BCP Sleeve
J2320.180	Drill Bit with Quick Coupling, 2.8 mm x 180 mm	J0240.009	Tap, 3.5 mm
J2430.180	Drill Bit, 2.8 mm x 180 mm, Cannulated	J0370.001	Torque Limiting Screw Driver 3.5 mm
J0740.004	Drill Sleeve For Twin Lock-BCP, 2.8 mm	J0190.010	Instrument Box
J0510.001	Guide Wire Sleeve, 1.5 mm	J0220.003	Implant Tray
J1880.150	Guide Wire, 1.5 mm x 150 mm (Simple)	J0220.004	Implant Tray
J1930.150	Guide Wire, 1.5 mm x 150 mm(Threaded)	J0220.005	Implant Tray
J2520.150	K Wire, Simple, 2.0 mm x 150 mm	J0221.006	Implant Tray
J0840.001	Screw Driver Shaft, 2.5 mm, Hexagonal	J0222.006	Implant Tray
J0140.009	Screw Driver, 2.5 mm , Hexagonal	J0200.016	COMPLETE INSTRUMENT SET FOR 3.5 MM LOCKING SYSTEM
17. INSTRUMENT SET FOR SMALL FRAGMENT 3.5 MM/2.7 MM SYSTEM			
J0030.004	Depth Gauge, 2.7/3.5 mm	J0840.004	Screw Driver Shaft, 2.7 mm, Star Drive
J0730.004	Double Drill Guide Sleeve 2.5 mm / 3.5 mm	J0140.011	Screw Driver, 2.7 mm, Star Drive
J0730.003	Double Drill Guide Sleeve 2.0 mm / 2.7 mm	J0880.001	Screw Holding Device, 2.7 mm, Star Drive



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Certificate of Compliance

Appendix-IX

Appendix to Certificate no.:- **CE-1888**

Manufacturer
Address

:- **SIGMA SURGICAL PRIVATE LIMITED**
:- **Survey No. 1636/1, Opp. Bharat Petroleum, Indore Highway, Village - Kuha, Taluka - Daskroi, Ahmedabad - 382438, Gujarat, India**

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71-75 Shelton Street, Covent Garden, London, WC2H 9JQ, United Kingdom
Website:- www.ukcertifications.org.uk, email:- info@ukcertifications.org.uk
Company No. 11847851



This certificate referred to above covers the following products like:

Products: -

J2300.150	Drill Bit with Quick Coupling, 2.5 mm x 150 mm	J0880.002	Screw Holding Device, 3.5 mm, Hexagonal
J2300.200	Drill Bit with Quick Coupling, 2.5 mm x 200 mm	J0280.003	T handle With Quick Coupling For Drill/ Tap
J2320.180	Drill Bit with Quick Coupling, 2.8 mm x 180 mm	J0900.001	T Handle For Twin Lock-BCP Sleeve
J2120.150	Drill Bit, 2.0 mm x 150 mm	J0240.008	Tap, 2.7 mm
J0740.002	Drill Sleeve For Twin Lock-BCP, 2.0 mm	J0240.009	Tap, 3.5 mm
J0740.003	Drill Sleeve For Twin Lock-BCP, 2.5 mm	J0620.001	Torque Limiting Wrench 2.7 / 2.4 mm WITH Quick Coupling
J0740.004	Drill Sleeve For Twin Lock-BCP, 2.8 mm	J0370.001	Torque Limiting Screw Driver 3.5 mm
J2520.150	K Wire, Simple, 2.0 mm x 150 mm	J0190.011	Instrument Box
J0840.001	Screw Driver Shaft, 2.5 mm, Hexagonal	J0200.017	COMPLETE INSTRUMENT SET FOR SMALL FRAGMENT 3.5 MM/2.7 MM SYSTEM
J0140.009	Screw Driver, 2.5 mm, Hexagonal		
18. INSTRUMENT SET FOR TWIN LOCK-BCP DISTAL RADIUS PLATE			
J0030.004	Depth Gauge, 2.7mm /3.5 mm	J0880.002	Screw Holding Device, 3.5 mm, Hexagonal
J0730.003	Double Drill Guide Sleeve 2.0 mm / 2.7 mm	J0900.001	T Handle For Twin Lock-BCP Sleeve
J0730.004	Double Drill Guide Sleeve 2.5 mm / 3.5 mm	J0280.003	T handle With Quick Coupling For Drill/ Tap
J2280.150	Drill Bit with Quick Coupling, 2.0 mm x 150 mm	J0240.008	Tap, 2.7 mm
J2300.150	Drill Bit with Quick Coupling, 2.5 mm x 150 mm	J0240.009	Tap, 3.5 mm
J2320.180	Drill Bit with Quick Coupling, 2.8 mm x 180 mm	J0620.001	Torque Limiting Wrench 2.7 / 2.4 mm WITH Quick Coupling
J0740.002	Drill Sleeve For Twin Lock-BCP, 2.0 mm	J0370.001	Torque Limiting Screw Driver 3.5 mm
J0740.004	Drill Sleeve For Twin Lock-BCP, 2.8 mm	J0220.012	Implant Tray
J2520.150	K Wire, Simple, 2.0 mm x 150 mm	J0190.012	Instrument Box
J0840.001	Screw Driver Shaft, 2.5 mm, Hexagonal	J0200.018	COMPLETE INSTRUMENT SET FOR TWIN LOCK-BCP DISTAL RADIUS PLATES
J0140.009	Screw Driver, 2.5 mm, Hexagonal	J0730.002	Double Drill Guide Sleeve 1.8 mm / 2.4 mm
J0840.004	Screw Driver Shaft, 2.7 mm, Star Drive	J2270.150	Drill Bit with Quick Coupling, 1.8 mm x 150 mm
J0140.011	Screw Driver, 2.7 mm, Star Drive	J0740.001	Drill Sleeve For Twin Lock-BCP, 1.8 mm
J0880.001	Screw Holding Device, 2.7 mm, Star Drive	J0240.007	Tap, 2.4 mm
19. INSTRUMENT SET FOR TWIN LOCK-BCP DITSAL HUMERAL PLATE			
J0240.005	Tap, Cannulated, 4.0 mm	J0140.009	Screw Driver, 2.5 mm, Hexagonal
J0030.004	Depth Gauge, 2.7mm /3.5 mm	J0840.004	Screw Driver Shaft, 2.7 mm, Star Drive
J0730.003	Double Drill Guide Sleeve 2.0 mm / 2.7 mm	J0140.012	Screw Driver, Cannulated, 2.5 mm, Hexagonal
J0730.004	Double Drill Guide Sleeve 2.5 mm / 3.5 mm	J0140.011	Screw Driver, 2.7 mm, Star Drive
J2420.150	Drill Bit, 2.7 mm x 150 mm, Cannulated	J0880.001	Screw Holding Device, 2.7 mm, Star Drive
J2280.150	Drill Bit with Quick Coupling, 2.0 mm x 150 mm	J0880.002	Screw Holding Device, 3.5 mm, Hexagonal
J2300.150	Drill Bit with Quick Coupling, 2.5 mm x 150 mm	J0900.001	T Handle For Twin Lock-BCP Sleeve
J2320.180	Drill Bit with Quick Coupling, 2.8 mm x 180 mm	J0280.003	T handle With Quick Coupling For Drill/ Tap
J0740.002	Drill Sleeve For Twin Lock-BCP, 2.0 mm	J0240.008	Tap, 2.7 mm
J0740.004	Drill Sleeve For Twin Lock-BCP, 2.8 mm	J0240.009	Tap, 3.5 mm
J1870.150	Guide Wire, 1.2 mm x 150 mm (Simple)	J0620.001	Torque Limiting Wrench 2.7 / 2.4 mm WITH Quick Coupling
J1920.150	Guide Wire, 1.2 mm x 150 mm (Threaded)	J0370.001	Torque Limiting Screw Driver 3.5 mm
J2520.150	K Wire, Simple, 2.0 mm x 150 mm	J0190.013	Instrument Box
J0840.001	Screw Driver Shaft, 2.5 mm, Hexagonal	J0200.019	COMPLETE INSTRUMENT SET FOR TWIN LOCK-BCP DISTAL HUMERAL PLATES



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Certificate of Compliance

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Appendix-X

Appendix to Certificate no.:- CE-1888

Manufacturer

Address

Signature

:- SIGMA SURGICAL PRIVATE LIMITED
:- Survey No. 1636/1, Opp. Bharat Petroleum, Indore Highway, Village - Kuha, Taluka - Daskroi, Ahmedabad - 382433, Gujarat, India



This certificate referred to above covers the following products like:

Products: -

20. INSTRUMENT SET FOR 5.0 MM/4.5 MM LOCKING SYSTEM			
J0030.005	Depth Gauge, 4.5 mm	J0840.002	Screw Driver Shaft, 3.5 mm, Hexagonal
J0440.008	Direct Measuring Device	J0140.007	Screw Driver, 3.5 mm, Hexagonal
J0730.005	Double Drill Guide Sleeve 3.2 mm / 4.5 mm	J0880.003	Screw Holding Device, 5.0 mm, Hexagonal
J2340.150	Drill Bit with Quick Coupling, 3.2 mm X 150 mm	J0280.003	T handle With Quick Coupling For Drill/ Tap
J2370.225	Drill Bit with Quick Coupling, 4.3 mm x 225 mm	J0900.001	T Handle For Twin Lock-BCP Sleeve
J2440.200	Drill Bit, 4.3 mm x 200 mm, Cannulated	J0240.004	Tap, 4.5 mm
J2220.200	Drill Bit, 4.5 mm x 200 mm	J0240.010	Tap, 6.5 mm
J0510.002	Guide Wire Sleeve, 2.0 mm	J0370.002	Torque Limiting Screw Driver 5.0 mm
J0740.006	Drill Sleeve For Twin Lock-BCP, 4.3 mm	J0210.006	Implant Box
J1890.230	Guide Wire, 2.0 mm x 230 mm (Simple)	J0220.007	Implant Tray
J1940.230	Guide Wire, 2.0 mm x 230 mm (Threaded)	J0220.008	Implant Tray
J2520.150	K Wire, Simple, 2.0 mm x 150 mm	J0220.009	Implant Tray
J0840.005	Screw Driver Shaft, Cannulated, 5.0 mm, Hexagonal	J0190.014	Instrument Box
J0140.008	Screw Driver, Cannulated, 3.5 mm, Hexagonal	J0200.020	COMPLETE INSTRUMENT SET FOR 5.0 MM/ 4.5 MM LOCKING SYSTEM
21. LARGE FRAGMENT INSTRUMENT SET			
J0030.005	Depth gauge, 4.5 mm	J0140.007	Screw Driver, 3.5 mm, Hexagonal
J0730.005	Double Drill Guide Sleeve 3.2 mm / 4.5 mm	J0880.003	Screw Holding Device, 5.0 mm, Hexagonal
J2340.150	Drill Bit with Quick Coupling, 3.2 mm x 150 mm	J0280.003	T handle With Quick Coupling For Drill/ Tap
J2340.200	Drill Bit with Quick Coupling, 3.2 mm x 200 mm	J0900.001	T Handle For Twin Lock-BCP Sleeve
J2370.225	Drill Bit with Quick Coupling, 4.3 mm x 225 mm	J0240.004	Tap, 4.5 mm
J0740.005	Drill Sleeve For Twin Lock-BCP, 3.2 mm	J0370.002	Torque Limiting Screw Driver 5.0 mm
J0740.006	Drill Sleeve For Twin Lock-BCP, 4.3 mm	J0190.015	Instrument Box
J2520.150	K Wire, Simple, 2.0 mm x 150 mm	J0200.021	COMPLETE INSTRUMENT SET FOR LARGE FRAGMENT
J0840.002	Screw Driver Shaft, 3.5 mm, Hexagonal		
22. INSTRUMENT SET FOR TWIN LOCK-BCP SCREW, 3.7 MM(CANNULATED) SYSTEM			
J0440.007	Direct Measuring Device	J1930.150	Guide Wire, 1.5 mm x 150 mm (Threaded)
J2430.180	Drill Bit, 2.8 mm x 180 mm, Cannulated	J0140.010	Screw Driver, Cannulated, 3.7 mm
J0510.001	Guide Wire Sleeve, 1.5 mm	J0840.003	Screw Driver Shaft, Cannulated, 3.7 mm, Hexagonal
J1880.150	Guide Wire, 1.5 mm x 150 mm (Simple)		
23. INSTRUMENT SET FOR TWIN LOCK-BCP SCREW, 5.0 MM(CANNULATED) SYSTEM			
J0440.008	Direct Measuring Device	J1940.230	Guide Wire, 2.0 mm x 230 mm (Threaded)
J2440.200	Drill Bit, 4.3 mm x 200 mm, Cannulated	J0840.005	Screw Driver Shaft, Cannulated, 5.0 mm, Hexagonal
J0510.002	Guide Wire Sleeve, 2.0 mm	J0140.008	Screw Driver, Cannulated, 3.5 mm, Hexagonal
J1890.230	Guide Wire, 2.0 mm x 230 mm (Simple)		
24. INSTRUMENT SET FOR CANNULATED CANCELLOUS BONE SCREW 4.0 MM			
J0240.005	Tap, Cannulated, 4.0 mm	J0910.001	Parallel Guide
J0440.009	Direct Measuring Device	J0140.012	Screw Driver, Cannulated, 2.5 mm, Hexagonal
J2420.150	Drill Bit, 2.7 mm x 150 mm, Cannulated	J0190.028	Instrument Box



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Certificate of Compliance

Appendix-XI

Appendix to Certificate no.:- CE-1888

Manufacturer :- SIGMA SURGICAL PRIVATE LIMITED
Address :- Survey No. 1636/1, Opp. Bharat Petroleum, Indore Highway, Village - Kuha, Taluka - Daskroi, Ahmedabad - 382433, Gujarat, India

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 Website:- www.ukcertifications.org.uk, email:- info@ukcertifications.org.uk
 Company No. 11847851



This certificate referred to above covers the following products like:

Products: -

J1870.150	Guide Wire, 1.2 mm x 150 mm (Simple)	J0200.022	COMPLETE INSTRUMENT SET FOR CANNULATED CANCELLOUS BONE SCREW 4.0 MM
J1920.150	Guide Wire, 1.2 mm x 150 mm (Threaded)		
25. INSTRUMENT SET FOR CANNULATED CANCELLOUS BONE SCREW 6.5 MM			
J0240.006	Tap, Cannulated, 6.5 mm	J1940.230	Guide Wire, 2.0 mm x 230 mm (Threaded)
J0920.001	Counter Sink, 6.5 mm CC	J0910.002	Parallel Guide
J0440.010	Direct Measuring Device	J0140.008	Screw Driver, Cannulated, 3.5 mm, Hexagonal
J2450.200	Drill bit, 4.5 mm x 200 mm, Cannulated	J0190.029	Instrument Box
J1890.230	Guide Wire, 2.0 mm x 230 mm (Simple)	J0200.023	COMPLETE INSTRUMENT SET FOR CANNULATED CANCELLOUS BONE SCREW 6.5 MM
26. INSTRUMENT SET FOR HARP SCREW			
J0440.011	Direct Measuring Device	J0140.013	Screw Driver, Cannulated, 2.0 mm, Hexagonal
J0730.001	Double Drill Sleeve, 1.0 mm / 2.0 mm	J0230.003	Bone Drill, Trapazium, Cannulated
J2410.100	Drill Bit, 2.0 mm x 100 mm, Cannulated	J0190.016	Instrument Box
J2070.150	Guide Wire, 1.0 mm X 150 mm (Simple)	J0200.024	COMPLETE INSTRUMENT SET FOR HARP SCREW
J2080.150	Guide Wire, 1.0 mm X 150 mm (Threaded)		
27. INSTRUMENT SET FOR TWIN LOCK-BCP PROXIMAL FEMORAL PLATE			
J0440.012	Direct Measuring Device	J2370.225	Drill Bit with Quick Coupling, 4.3 mm x 225 mm
J2460.300	Drill Bit, 5.5 mm x 300 mm, Cannulated	J0740.006	Drill Sleeve For Twin Lock-BCP, 4.3 mm
J0740.007	Drill Sleeve For Twin Lock-BCP, 5.5 mm	J0140.014	Screw Driver, Cannulated, 4.5 mm, Hexagonal
J0510.003	Guide Wire Sleeve, 5.5 mm X 2.5 mm	J0140.007	Screw Driver, 3.5 mm, Hexagonal
J1900.230	Guide Wire, 2.5 mm x 230 mm (Simple)	J0190.017	Instrument Box
J1950.230	Guide Wire, 2.5 mm x 230 mm (Threaded)	J0200.025	COMPLETE INSTRUMENT SET FOR TWIN LOCK-BCP PROXIMAL FEMORAL PLATE
28. INSTRUMENT SETS FOR TWIN LOCK-BCP LEXA PROXIMAL FEMORAL PLATE			
J0440.013	Direct Measuring Device	J0140.015	Screw Driver, Cannulated, 6.0 mm
J2470.225	Drill Bit, 4.7 mm x 225 mm, Cannulated	J0840.006	Screw Driver Shaft, Cannulated, 6.0 mm, Hexagonal
J0510.004	Guide Wire Sleeve, 2.5 mm	J0900.001	T Handle For Twin Lock-BCP Sleeve
J1900.230	Guide Wire, 2.5 mm x 230 mm (Simple)	J0190.018	Instrument Box
J1950.230	Guide Wire, 2.5 mm x 230 mm (Threaded)	J0200.026	COMPLETE INSTRUMENT SET FOR TWIN LOCK-BCP LEXA PROXIMAL FEMORAL PLATE
29. INSTRUMENT SET FOR TWIN LOCK-BCP STELIOS FIX PLATE			
J0940.001	Bone Spreder	J0980.001	Osteotome Chisel, 10 mm
J0950.001	Bone Spreder Soft Lock	J0980.002	Osteotome Chisel, 15 mm
J0030.005	Depth Gauge, 4.5 mm	J0980.003	Osteotome Chisel, 20 mm
J0730.005	Double Drill Guide Sleeve 3.2 mm / 4.5 mm	J0980.004	Osteotome Chisel, 25 mm
J2340.150	Drill Bit with Quick Coupling, 3.2 mm x 150 mm	J0140.007	Screw Driver, 3.5 mm, Hexagonal
J2370.225	Drill Bit with Quick Coupling, 4.3 mm x 225 mm	J0990.001	Tibia Clip, Small
J0740.006	Drill Sleeve For Twin Lock-BCP, 4.3 mm	J1000.001	Vertical Pole
J0960.001	Femoral Clip Large	J0370.002	Torque Limiting Screw Driver 5.0 mm



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Certificate of Compliance

Appendix-XII

Appendix to Certificate no.:- **CE-1888**

Manufacturer

:- **SIGMA SURGICAL PRIVATE LIMITED**

Address

:- **Survey No. 1636/1, Opp. Bharat Petroleum, Indore**

Highway, Village - Kuha, Taluka - Daskroi,

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71-75 Shelton Street, Covent Garden, London, WC2H 9JQ, United Kingdom

Website:- www.ukcertifications.org.uk, email:- info@ukcertifications.org.uk

Company No. 11847851



This certificate referred to above covers the following products like:

Products: -

J0970.001	Gap Measuring Device	J0190.019	Instrument Box
J0090.004	Hammer	J0200.027	COMPLETE INSTRUMENT SET FOR TWIN LOCK-BCP STELIOS FIX PLATE
J2530.280	K Wire, Simple, 2.5 mm x 280 mm		
30. INSTRUMENT SET FOR ACL/PCL RECONSTRUCTION			
J1010.001	Angle Bullete	J1090.001	Graft passing 2.4mm drill bit
J1020.001	Arthroscopic Probe	J1100.001	Graft passing pin (Beadth pin)
J1030.001	Cannulated Femoral Flowertip Reamer, Dia.6.0mm	J1110.001	Graft Prep Station
J1030.002	Cannulated Femoral Flowertip Reamer, Dia.7.0mm	J1120.001	Graft Sizing Block
J1030.003	Cannulated Femoral Flowertip Reamer, Dia.8.0mm	J0190.025	Instrument Box
J1030.004	Cannulated Femoral Flowertip Reamer, Dia.9.0mm	J0490.005	Impactor For spiked ligament staple
J1030.005	Cannulated Femoral Flowertip Reamer, Dia.10.0mm	J0350.001	Main zig
J1030.006	Cannulated Femoral Flowertip Reamer, Dia.11.0mm	J0310.002	Microfracture AWL,30'
J1030.007	Cannulated Femoral Flowertip Reamer, Dia.12.0mm	J0310.003	Microfracture AWL,45'
J0140.016	Cannulated screwdriver For BioLock interference screws	J0310.004	Microfracture AWL,90'
J1040.001	Cannulated Tibial Reamer, Dia.6.0mm	J1130.001	Pcl Femoral
J1040.002	Cannulated Tibial Reamer, Dia.7.0mm	J1140.001	Pcl Tibial
J1040.003	Cannulated Tibial Reamer, Dia.8.0mm	J1050.002	Straight Rasp
J1040.004	Cannulated Tibial Reamer, Dia.9.0mm	J1160.001	Tendon Stripper, Closed end, 6mm
J1040.005	Cannulated Tibial Reamer, Dia.10.0mm	J1170.001	Tendon Stripper, Open end, 7mm
J1040.006	Cannulated Tibial Reamer, Dia.11.0mm	J1180.001	T-Handle For Tunnel Dilators
J1040.007	Cannulated Tibial Reamer, Dia.12.0mm	J1190.001	Tunnel Dilator, 7mm
J2610.001	Endoscopic Reamer, Dia. 4.5 mm	J1190.002	Tunnel Dilator, 8mm
J1050.001	Convex Rasp	J1190.003	Tunnel Dilator, 9mm
J0030.008	Depth Gauge For ACL/PCL reconstruction	J1200.001	Tunnel Plug, 7-8 mm
J1060.001	Elbow aimer	J1200.002	Tunnel Plug, 8-9 mm
J1070.001	Femoral Aimer, 5mm	J1200.003	Tunnel Plug, 9-10 mm
J1070.002	Femoral Aimer, 7mm	J0200.028	COMPLETE INSTRUMENT SET FOR ACL/PCL RECONSTRUCTION
J1080.001	Femoral PCL Elevator		
31. INSTRUMENT SET FOR AMP SYSTEM			
J1210.001	Head Extractor	J1050.004	Rasp with Tommy Bar (Medium)
J1220.001	Head Guage	J1050.005	Rasp with Tommy Bar (Small)
J0490.006	Head Impactor with Nylon Phase	J0190.020	Instrument Box
J1230.001	Murphy Skid	J0200.029	COMPLETE INSTRUMENT SET FOR AMP SYSTEM
J1050.003	Rasp with Tommy Bar (Large)		



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Certificate of Compliance

Appendix-XIII

Appendix to Certificate no.:- **CE-1888**

Manufacturer :- **SIGMA SURGICAL PRIVATE LIMITED**

Address :- **Survey No. 1636/1, Opp. Bharat Petroleum, Indore Highway, Village - Kuha, Taluka - Daskroi, Ahmedabad - 382433, Gujarat, India.**



This certificate referred to above covers the following products like:

Products: -

32. INSTRUMENT SET FOR BI POLAR SYSTEM			
J1250.001	Box Chissel Big	J1280.006	Trial Cup Set, 42 mm
J1250.002	Box Chissel Small	J1280.007	Trial Cup Set, 43 mm
J0010.004	Diamond Point AWL	J1280.008	Trial Cup Set, 44 mm
J1210.001	Head Extractor	J1280.009	Trial Cup Set, 45 mm
J1220.001	Head Guage	J1280.010	Trial Cup Set, 46 mm
J0490.006	Head Impactor with Nylon Phase	J1280.011	Trial Cup Set, 47 mm m)
J1230.001	Murphy Skid	J1280.012	Trial Cup Set, 48 mm
J1050.006	Rasp with tommy bar	J1280.013	Trial Cup Set, 49 mm
J1260.001	Shaft Reamer Big	J1280.014	Trial Cup Set, 50 mm
J1260.002	Shaft Reamer Serrated	J1280.015	Trial Cup Set, 51 mm
J1260.003	Shaft Reamer Small	J1280.016	Trial Cup Set, 52 mm
J1270.001	Stem Inroducer	J1280.017	Trial Cup Set, 53 mm
J1280.001	Trial Cup Set, 37 mm	J1280.018	Trial Cup Set, 54 mm
J1280.002	Trial Cup Set, 38 mm	J1280.019	Trial Cup Set, 55 mm
J1280.003	Trial Cup Set, 39 mm	J1290.001	Trial Stem
J1280.004	Trial Cup Set, 40 mm	J0190.021	Instrument Box
J1280.005	Trial Cup Set, 41 mm	J0200.030	COMPLETE INSTRUMENT SET FOR BI-POLAR SYSTEM
33. INSTRUMENT SET FOR SPINE			
J0310.005	Bone AWL	J1430.001	Rod Template 5.5 mm
J0310.006	Bone AWL, Straight	J1440.001	Rod Holder
J1300.001	Bending Iron	J1450.001	Rod Pusher
J1310.001	Break of Iron	J1460.001	Reduction Foreceps
J1320.001	Break of Protection	J1470.001	Rod Rotation Wrench
J1330.001	Compressor	J1480.001	Rod Holder Clamp
J0310.007	Curved AWL	J0140.017	Screw Driver For Cross Link
J1340.001	Distractor	J0370.003	Torque Limiting Screw Driver
J1350.001	D Torque	J0240.011	Tap, 4.5 mm
J1360.001	French Bender	J0240.012	Tap, 5.5 mm
J0380.001	Mono Axial Screw Driver	J0240.013	Tap, 6.5 mm
J1370.001	Nut Holder Elastic	J0240.014	Tap, 7.5 mm
J1380.001	Nuts Driver	J0280.004	Quick Coupling " T " Handle
J1390.001	Nuts Driver Shaft	J0690.002	ROD CUTTER
J0380.002	Poly Axial Screw Driver	J0190.022	Instrument Box
J1400.001	Pedicle Localizer	J0210.005	Implant Box
J1410.001	Probe	J0200.031	COMPLETE INSTRUMENT SET FOR SPINE
J1420.001	Rod Push Forceps		
34. INSTRUMENT SET FOR CAGE			
J1490.001	Bone Curette	J1570.006	Shaver For Intervertebral Discs , 12.0 mm
J1490.002	Bone Curette 45° Angled	J1570.007	Shaver For Intervertebral Discs , 13.0 mm
J1490.003	Bone Curette 90°	J1490.007	Bone Curette Side 45°
J1500.001	Cage Holder	J1280.020	Trail Implant For Onyx cage, 8.0 mm
J1491.004	Curette Rectangular angled(Left) bayoneted	J1280.021	Trail Implant For Onyx cage, 9.0 mm
J1492.004	Curette Rectangular angled(Right)	J1280.022	Trail Implant For Onyx cage, 10.0 mm



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Certificate of Compliance

Appendix-XIV

Appendix to Certificate no.:- **CE-1888**

Manufacturer :- **SIGMA SURGICAL PRIVATE LIMITED**

Address :- **Survey No. 1636/1, Opp. Bharat Petroleum, Indore Highway, Village - Kuha, Taluka - Daskroi, Ahmedabad - 382438, Gujarat, India**

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Website:- www.ukcertifications.org.uk, email:- info@ukcertifications.org.uk
Company No. 11847851



This certificate referred to above covers the following products like:

Products: -

J1520.001	End Plate Elevator, bayoneted	J1280.023	Trail Implant For Onyx cage, 11.0 mm
J0500.001	Impactor	J1280.024	Trail Implant For Onyx cage, 12.0 mm
J0500.002	Impactor Curved Standard bayoneted(Small)	J1280.025	Trail Implant For Onyx cage, 13.0 mm
J1530.001	Osteotome Straight	J1280.026	Trail Implant For Onyx cage, 14.0 mm
J0280.005	Quick Coupling Holder	J1280.027	Trail Implant For Triton cage, 8.0 mm
J1050.007	Rasp Dual Sided bayoneted	J1280.028	Trail Implant For Triton cage, 9.0 mm
J1050.008	Rasp Dual Sided Impactor bayoneted(Small)	J1280.029	Trail Implant For Triton cage, 10.0 mm
J1050.009	Rasp Dual Sider angle bayoneted	J1280.030	Trail Implant For Triton cage, 11.0 mm
J1490.005	Ring Curette Curved bayoneted	J1280.031	Trail Implant For Triton cage, 12.0 mm
J1490.006	Ring Curette Straight bayoneted	J1280.032	Trail Implant For Triton cage, 13.0 mm
J1570.001	Shaver For Intervertebral Discs , 7.0 mm	J1280.033	Trail Implant For Triton cage, 14.0 mm
J1570.002	Shaver For Intervertebral Discs , 8.0 mm	J1610.001	Packing Block For Onyx Cage
J1570.003	Shaver For Intervertebral Discs , 9.0 mm	J1610.002	Packing Block For Triton Cage
J1570.004	Shaver For Intervertebral Discs , 10.0 mm	J0190.023	Instrument Box
J1570.005	Shaver For Intervertebral Discs , 11.0 mm	J0200.032	COMPLETE INSTRUMENT SET FOR CAGE
35. INSTRUMENT SET FOR TWIN LOCK-BCP STRING READY PROXIMAL GT PLATE			
J0690.003	Cable Cutter	J0490.007	Impactor
J1630.001	Cable Lock Front, 1.80 mm	J0490.008	Impactor
J1620.001	Cable Lock Back, 1.80 mm	J0140.018	Screw Driver, 3.0 mm,
J1640.001	Cable Passer-Medium	J0210.014	Instrument Box
J1640.002	Cable Passer-Large	J0190.024	Instrument Box
J1640.003	Cable Passer-45°	J0200.033	COMPLETE INSTRUMENT SET FOR TWIN LOCK-BCP STRING READY PROXIMAL GT PLATE
J1650.001	Cable Tensioner		
36. INSTRUMENT SET FOR EIGHT PLATE			
J0730.008	Double Drill Guide Sleeve 1.6 mm / 3.2 mm	J2700.150	K Wire, Simple, 1.6 mm x 150 mm
J2670.150	Drill Bit, 3.2 mm x 150 mm, Cannulated	J0190.026	Instrument Box
J2680.150	Guide Wire, 1.6 mm x 150 mm (Simple)	J0200.035	COMPLETE INSTRUMENT SET FOR EIGHT PLATE
J2690.150	Guide Wire, 1.6 mm x 150 mm (Threaded)		
37. COMPLETE INSTRUMENT SET FOR CERVICAL EXPANDABLE CAGE			
J0030.009	Depth Gauge (For cervical Expandable Cage)	J0760.001	Bone Awl
J2300.200.01	Drill Bit with Quick Coupling, 2.5 mm x 200 mm	J0770.001	Cage Driver
J0140.019	Screw Driver, 2.5 mm with sleeve, Hexagonal	J0820.001	Cage Gripper
J0140.020	Screw Driver, 2.5 mm, Hexagonal	J0850.001	Fixed Needle, 2.0 mm
J2720.001	Drill Sleeve, Dia. 2.5 mm, Fixed angle	J0850.002	Fixed Needle, 3.0 mm
J2720.002	Drill Sleeve, Dia. 2.5 mm, Modular Angle	J0860.001	Bone Graft Pusher
J2730.001	Fixed Needle Holder	J0280.006	Quick Coupling Handle
J0680.001	Cage Pusher, 18 mm	J0190.027	Instrument Box
J0680.002	Cage Pusher, 22 mm	J0200.036	COMPLETE INSTRUMENT SET FOR CERVICAL EXPANDABLE CAGE



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Certificate of Compliance

Appendix-XV

Appendix to Certificate no.:- **CE-1888**

Manufacturer :- **SIGMA SURGICAL PRIVATE LIMITED**
Address :- **Survey No. 1636/1, Opp. Bharat Petroleum, Indore Highway, Village - Kuha, Taluka - Daskroi, Ahmedabad - 382433, Gujarat, India**



Certification & Inspection



This certificate referred to above covers the following products like:

Products: -

38. GENRAL INSTRUMENT			
J0010.005	Bone AWL	J2120.100	Drill Bit, 2.0 mm x 100 mm
J2630.014	Guide Wire, Trocar Point, 2.0 mm x 14" (Simple)	J2120.125	Drill Bit, 2.0 mm x 125 mm
J2640.014	Guide Wire, Trocar Point, 2.0 mm x 14" (Threaded)	J2120.150	Drill Bit, 2.0 mm x 150 mm
J2600.230	Guide Wire, 1.8 mm X 230 mm (Threaded)	J2130.100	Drill Bit, 2.4 mm x 100 mm
J2620.400	Guide Wire, 3.2 mm x 400 mm (Simple)	J2130.125	Drill Bit, 2.4 mm x 125 mm
J2650.450	Guide Wire, 1.4 mm x 450 mm (Simple)	J2130.150	Drill Bit, 2.4 mm x 150 mm
J2660.450	Guide Wire, 1.4 mm x 450 mm (Threaded)	J2140.100	Drill Bit, 2.5 mm x 100 mm
J2710.150	K Wire, Threaded, 1.6 mm x 150 mm	J2140.150	Drill Bit, 2.5 mm x 150 mm
J0250.006	Guide Wire Sleeve, 8.0 mm x 2.0 mm	J2140.180	Drill Bit, 2.5 mm x 180 mm
J0250.007	Guide Wire Sleeve, 10.0 mm x 2.5 mm	J2140.200	Drill Bit, 2.5 mm x 200 mm
J1661.001	Block Twin Lock-BCP Distal Femoral Plate(Left)	J2150.100	Drill Bit, 2.7 mm x 100 mm
J1662.001	Block Twin Lock-BCP Distal Femoral Plate(Right)	J2150.125	Drill Bit, 2.7 mm x 125 mm
J1671.001	Block For Twin Lock-BCp Distal Medial Tibial Plate(Left)	J2150.150	Drill Bit, 2.7 mm x 150 mm
J1672.001	Block For Twin Lock-BCp Distal Medial Tibial Plate(Right)	J2150.200	Drill Bit, 2.7 mm x 200 mm
J1681.001	Block For Twin Lock-BCP Lateral Tibial Plate(Left)	J2150.250	Drill Bit, 2.7 mm x 250 mm
J1682.001	Block For Twin Lock-BCP Lateral Tibial Plate(Right)	J2160.180	Drill Bit, 2.8 mm x 180 mm
J1690.001	Block For Twin Lock-BCP Proton Proximal Humerus Plate(Philos)	J2170.150	Drill Bit, 3.0 mm x 150 mm
J1700.001	Sleeve For Block (Twin Lock-BCP Distal Femoral Plate)	J2180.100	Drill Bit, 3.2 mm x 100 mm
J1700.001	Sleeve For Block (Twin Lock-BCP Lateral Tibial Plate)	J2180.150	Drill Bit, 3.2 mm x 150 mm
J1720.001	Sleeve For Block (Twin Lock-BCP Ditsal Medial Tibial Plate)	J2180.195	Drill Bit, 3.2 mm x 195 mm
J1720.001	Sleeve For Block (Twin Lock-BCP Proton Proximal Humerus Plate)	J2180.200	Drill Bit, 3.2 mm x 200 mm
J0030.006	Depth Gauge, 2.4 mm	J2180.170	Drill Bit, 3.2 mm x 170 mm
J0030.007	Depth Gauge, 2.7 mm	J2180.250	Drill Bit, 3.2 mm x 250 mm
J0730.006	Loaded & Neutral Drill Guide Sleeve, 2.5 / 3.5 mm (For 3.5 mm screw)	J2180.300	Drill Bit, 3.2 mm x 300 mm
J0730.007	Loaded & Neutral Drill Guide Sleeve, 3.2 / 4.5 mm (For 4.5 mm screw)	J2190.100	Drill Bit, 3.5 mm x 100 mm
J1740.001	Screw Forcap	J2190.150	Drill Bit, 3.5 mm x 150 mm
J1750.001	Template Set, 3.5 mm	J2190.250	Drill Bit, 3.5 mm x 250 mm
J1750.002	Template Set, 4.5 mm	J2200.150	Drill Bit, 4.0 mm x 150 mm
J1760.001	Universal Nail Remover Set	J2200.170	Drill Bit, 4.0 mm x 170 mm
J1770.001	Bone Nibbler	J2200.300	Drill Bit, 4.0 mm x 300 mm
J0690.004	Bone Cutter	J2200.325	Drill Bit, 4.0 mm x 325 mm
J1780.001	Plate Bender, Small	J2210.200	Drill Bit, 4.3 mm x 200 mm
J1780.002	Plate Bender, Large	J2210.225	Drill Bit, 4.3 mm x 225 mm
Drill Bit		J2220.195	Drill Bit, 4.5 mm x 195 mm
J2090.075	Drill Bit, 1.0 mm x 75 mm	J2220.150	Drill Bit, 4.5 mm x 150 mm
J2090.100	Drill Bit, 1.0 mm x 100 mm	J2220.200	Drill Bit, 4.5 mm x 200 mm
J2100.075	Drill Bit, 1.5 mm x 75 mm	J2220.300	Drill Bit, 4.5 mm x 300 mm
J2100.100	Drill Bit, 1.5 mm x 100 mm	J2230.300	Drill Bit, 5.0 mm x 300 mm
J2110.100	Drill Bit, 1.8 mm x 100 mm	J2240.150	Drill Bit, 5.5 mm x 150 mm
J2110.125	Drill Bit, 1.8 mm x 125 mm		



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Certificate of Compliance

Appendix-XVI

Appendix to Certificate no.:- **CE-1888**

Manufacturer

:- **SIGMA SURGICAL PRIVATE LIMITED**

Address

:- **Survey No. 1636/1, Opp. Bharat Petroleum, Indore Highway, Village - Kuha, Taluka - Daskroi, Ahmedabad - 382435, Gujarat, India**

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Website:- www.ukcertifications.org.uk, email:- info@ukcertifications.org.uk
Company No. 11847851



Certification & Inspection



This certificate referred to above covers the following products like:

Products: -

Drill Bit with Quick Coupling			
J2250.075	Drill Bit with Quick Coupling, 1.0 mm x 75 mm	J2330.150	Drill Bit with Quick Coupling, 3.0 mm x 150 mm
J2250.100	Drill Bit with Quick Coupling, 1.0 mm x 100 mm	J2340.100	Drill Bit with Quick Coupling, 3.2 mm x 100 mm
J2260.075	Drill Bit with Quick Coupling, 1.5 mm x 75 mm	J2340.150	Drill Bit with Quick Coupling, 3.2 mm x 150 mm
J2260.100	Drill Bit with Quick Coupling, 1.5 mm x 100 mm	J2340.170	Drill Bit with Quick Coupling, 3.2 mm x 170 mm
J2270.100	Drill Bit with Quick Coupling, 1.8 mm x 100 mm	J2340.200	Drill Bit with Quick Coupling, 3.2 mm x 200 mm
J2270.125	Drill Bit with Quick Coupling, 1.8 mm x 125 mm	J2340.250	Drill Bit with Quick Coupling, 3.2 mm x 250 mm
J2270.150	Drill Bit with Quick Coupling, 1.8 mm x 150 mm	J2340.300	Drill Bit with Quick Coupling, 3.2 mm x 300 mm
J2280.100	Drill Bit with Quick Coupling, 2.0 mm x 100 mm	J2350.100	Drill Bit with Quick Coupling, 3.5 mm x 100 mm
J2280.125	Drill Bit with Quick Coupling, 2.0 mm x 125 mm	J2350.150	Drill Bit with Quick Coupling, 3.5 mm x 150 mm
J2280.150	Drill Bit with Quick Coupling, 2.0 mm x 150 mm	J2350.250	Drill Bit with Quick Coupling, 3.5 mm x 250 mm
J2290.100	Drill Bit with Quick Coupling, 2.4 mm x 100 mm	J2360.150	Drill Bit with Quick Coupling, 4.0 mm x 150 mm
J2290.125	Drill Bit with Quick Coupling, 2.4 mm x 125 mm	J2360.170	Drill Bit with Quick Coupling, 4.0 mm x 170 mm
J2290.150	Drill Bit with Quick Coupling, 2.4 mm x 150 mm	J2360.300	Drill Bit with Quick Coupling, 4.0 mm x 300 mm
J2300.100	Drill Bit with Quick Coupling, 2.5 mm x 100 mm	J2360.325	Drill Bit with Quick Coupling, 4.0 mm x 325 mm
J2300.150	Drill Bit with Quick Coupling, 2.5 mm x 150 mm	J2370.200	Drill Bit with Quick Coupling, 4.3 mm x 200 mm
J2300.180	Drill Bit with Quick Coupling, 2.5 mm x 180 mm	J2370.225	Drill Bit with Quick Coupling, 4.3 mm x 225 mm
J2300.200	Drill Bit with Quick Coupling, 2.5 mm x 200 mm	J2380.150	Drill Bit with Quick Coupling, 4.5 mm x 150 mm
J2310.100	Drill Bit with Quick Coupling, 2.7 mm x 100 mm	J2380.200	Drill Bit with Quick Coupling, 4.5 mm x 200 mm
J2310.150	Drill Bit with Quick Coupling, 2.7 mm x 150 mm	J2380.300	Drill Bit with Quick Coupling, 4.5 mm x 300 mm
J2310.200	Drill Bit with Quick Coupling, 2.7 mm x 200 mm	J2390.300	Drill Bit with Quick Coupling, 5.0 mm x 300 mm
J2310.250	Drill Bit with Quick Coupling, 2.7 mm x 250 mm	J2400.150	Drill Bit with Quick Coupling, 5.5 mm x 150 mm
J2320.180	Drill Bit with Quick Coupling, 2.8 mm x 180 mm		
Flexible Reamer with shaft			
J1790.001	Flexible Reamer with shaft, 8.0 mm	J1790.007	Flexible Reamer with shaft, 11.0 mm
J1790.002	Flexible Reamer with shaft, 8.5 mm	J1790.008	Flexible Reamer with shaft, 11.5 mm
J1790.003	Flexible Reamer with shaft, 9.0 mm	J1790.009	Flexible Reamer with shaft, 12.0 mm
J1790.004	Flexible Reamer with shaft, 9.5 mm	J1790.010	Flexible Reamer with shaft, 12.5 mm
J1790.005	Flexible Reamer with shaft, 10.0 mm	J1790.011	Flexible Reamer with shaft, 13.0 mm
J1790.006	Flexible Reamer with shaft, 10.5 mm	J1790.007	Flexible Reamer with shaft, 11.0 mm
J1790.001	Flexible Reamer with shaft, 8.0 mm		
Flexible Reamer Tip			
J1800.001	Flexible Reamer Tip, 8.0 mm	J1800.007	Flexible Reamer Tip, 11.0 mm
J1800.002	Flexible Reamer Tip, 8.5 mm	J1800.008	Flexible Reamer Tip, 11.5 mm
J1800.003	Flexible Reamer Tip, 9.0 mm	J1800.009	Flexible Reamer Tip, 12.0 mm
J1800.004	Flexible Reamer Tip, 9.5 mm	J1800.010	Flexible Reamer Tip, 12.5 mm
J1800.005	Flexible Reamer Tip, 10.0 mm	J1800.011	Flexible Reamer Tip, 13.0 mm
J1800.006	Flexible Reamer Tip, 10.5 mm		
J1810.001	Flexible Reamer Shaft		
Fix Reamer Solid			
J1820.001	Fix Reamer Solid, 3 mm	J1820.003	Fix Reamer Solid, 5 mm
J1820.002	Fix Reamer Solid, 4 mm		



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Certificate of Compliance

Appendix-XVII

Appendix to Certificate no.:- **CE-1888**

Manufacturer

:- **SIGMA SURGICAL PRIVATE LIMITED**

Address

:- **Survey No. 1636/1, Opp. Bharat Petroleum, Indore Highway, Village - Kuha, Taluka - Daskroi, Ahmedabad - 382433, Gujarat, India**

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Company No. 11847851



This certificate referred to above covers the following products like:

Products: -

Fix Reamer, Cannulated			
J1830.001	Fix Reamer, Cannulated, 6 mm	J1830.006	Fix Reamer, Cannulated, 11 mm
J1830.002	Fix Reamer, Cannulated, 7 mm	J1830.007	Fix Reamer, Cannulated, 12 mm
J1830.003	Fix Reamer, Cannulated, 8 mm	J1830.008	Fix Reamer, Cannulated, 13 mm
J1830.004	Fix Reamer, Cannulated, 9 mm	J1830.009	Fix Reamer, Cannulated, 5 mm
J1830.005	Fix Reamer, Cannulated, 10 mm		
Counter Sink			
J0920.002	Counter Sink, 3.5 mm / 4.0 mm	J0920.003	Counter Sink, 4.0 mm C.C.
J0920.001	Counter Sink, 4.5 mm / 6.5 mm		
K Wire, Simple, 150 mm			
J2480.150	K Wire, Simple, 1.0 mm x 150 mm	J2510.150	K Wire, Simple, 1.8 mm x 150 mm
J2490.150	K Wire, Simple, 1.1 mm x 150 mm	J2520.150	K Wire, Simple, 2.0 mm x 150 mm
J2500.150	K Wire, Simple, 1.5 mm x 150 mm	J2530.150	K Wire, Simple, 2.5 mm x 150 mm
K Wire, Simple, 300 mm			
J2480.300	K Wire, Simple, 1.0 mm x 300 mm	J2510.300	K Wire, Simple, 1.8 mm x 300 mm
J2490.300	K Wire, Simple, 1.1 mm x 300 mm	J2520.300	K Wire, Simple, 2.0 mm x 300 mm
J2500.300	K Wire, Simple, 1.5 mm x 300 mm	J2530.300	K Wire, Simple, 2.5 mm x 300 mm
K Wire, Threaded, 150 mm			
J2540.150	K Wire, Threaded, 1.0 mm x 150 mm	J2570.150	K Wire, Threaded, 1.8 mm x 150 mm
J2550.150	K Wire, Threaded, 1.1 mm x 150 mm	J2580.150	K Wire, Threaded, 2.0 mm x 150 mm
J2560.150	K Wire, Threaded, 1.5 mm x 150 mm	J2590.150	K Wire, Threaded, 2.5 mm x 150 mm
K Wire, Threaded, 300 mm			
J2540.300	K Wire, Threaded, 1.0 mm x 300 mm	J2570.300	K Wire, Threaded, 1.8 mm x 300 mm
J2550.300	K Wire, Threaded, 1.1 mm x 300 mm	J2580.300	K Wire, Threaded, 2.0 mm x 300 mm
J2560.300	K Wire, Threaded, 1.5 mm x 300 mm	J2590.300	K Wire, Threaded, 2.5 mm x 300 mm
K Wire, Simple, 280 mm			
J2480.280	K Wire, Simple, 1.0 mm x 280 mm	J2510.280	K Wire, Simple, 1.8 mm x 280 mm
J2490.280	K Wire, Simple, 1.1 mm x 280 mm	J2520.280	K Wire, Simple, 2.0 mm x 280 mm
J2500.280	K Wire, Simple, 1.5 mm x 280 mm	J2530.280	K Wire, Simple, 2.5 mm x 280 mm
K Wire, Threaded, 280 mm			
J2540.280	K Wire, Threaded, 1.0 mm x 280 mm	J2570.280	K Wire, Threaded, 1.8 mm x 280 mm
J2550.280	K Wire, Threaded, 1.1 mm x 280 mm	J2580.280	K Wire, Threaded, 2.0 mm x 280 mm
J2560.280	K Wire, Threaded, 1.5 mm x 280 mm	J2590.280	K Wire, Threaded, 2.5 mm x 280 mm
J0140.007	Screw Driver, 3.5 mm, Hexagonal	J0210.012	Implant Box (For 4.5 / 6.5 mm Screw)
J0210.007	Implant Box	J0590.001	Suture Anchor Screw Driver, 3.0 mm
J0210.008	Implant Box	J0590.002	Suture Anchor Screw Driver, 5.0 mm
J0210.009	Implant Box	J1840.001	Universal Joint Spaner
J0210.010	Implant Box (For 2.7 / 3.5 mm Screw)	J1850.001	Broken Nail Remover
J0210.011	Implant Box (For 3.5 / 4.0 mm Screw)		



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Certificate of Compliance

Appendix-XVIII

Appendix to Certificate no.:- **CE-1888**

Manufacturer :- **SIGMA SURGICAL PRIVATE LIMITED**

Address :- **Survey No. 1636/1, Opp. Bharat Petroleum, Indore Highway, Village - Kuha, Taluka - Daskroi, Ahmedabad - 382438, Gujarat, India**

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Website:- www.ukcertifications.org.uk, email:- info@ukcertifications.org.uk

Company No. 11847851



This certificate referred to above covers the following products like:

Products: -

Carbon Rod			
J1860.001	Carbon Rod, 11.0 mm x 150 mm	J1860.005	Carbon Rod, 11.0 mm x 350 mm
J1860.002	Carbon Rod, 11.0 mm x 200 mm	J1860.006	Carbon Rod, 11.0 mm x 400 mm
J1860.003	Carbon Rod, 11.0 mm x 250 mm	J1860.007	Carbon Rod, 11.0 mm x 450 mm
J1860.004	Carbon Rod, 11.0 mm x 300 mm	J1860.008	Carbon Rod, 11.0 mm x 500 mm
J2020.115	Guide Wire, 2.5 mm x 115 cm (Bullet Tips) (Titanium)	J0870.001	Flexible Entry Reamer, Dia. 15.50 mm
J2030.115	Guide Wire, 2.5 mm x 115 cm (Simple)(Titanium)	Z1310.001	LCP Drill Sleeve, Dia. 2.50 mm
J0200.034	COMPLETE INSTRUMENT SET FOR ENDERS NAIL	Z1320.001	LCP Drill Sleeve, Dia. 3.50 mm
J0010.006	Bone AWL, Cannulated	J0890.001	Screw Remover, Dia. 3.50 mm
J1880.230	Guide Wire, 1.5 mm x 230 mm (Simple)	J0890.002	Screw Remover, Dia. 4.50 mm
J1930.230	Guide Wire, 1.5 mm x 230 mm (Threaded)	J1920.230	Guide Wire, 1.2 mm x 230 mm (Threaded)
J1870.230	Guide Wire, 1.2 mm x 230 mm (Simple)		



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