



Notified Body No 1023  
**INSTITUTE FOR TESTING AND CERTIFICATION, Inc.**  
Zlín, Czech Republic – [www.itczlin.cz](http://www.itczlin.cz)

# EC CERTIFICATE

**No. 12 0102 QS/NB**

issued in compliance with the Council Directive 93/42/EEC as amended, which is implemented by the Czech Government Order No. 336/2004 (Collection of Laws), certifies that the products – medical devices of Class IIb, models

## Orthopaedic Implants, Spinal Implants

(For detailed specification refer to Annex, pages 2 - 8)

manufactured by company

### Nebula Surgical Pvt. Ltd.

**Registered Office:** B-35/36, Pramukha Swami Arcade, Malaviya Chowk, Dr. Yagnik Road, Rajkot - 360 001 Gujarat, India

**Work site:** G. I. D. C., G/739/740, Metoda, Rajkot - 360 021, Gujarat, India

are manufactured under conditions fulfilling the quality system requirements of Annex II, Section 3.2. of the Directive 93/42/EEC, as amended.

The Notified Body No. 1023 has performed an audit of the above products quality system covering the design, manufacture and final inspection of the certified products. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex II, Sections 3.3. and 5., of the Directive 93/42/EEC. The detailed description of the system parts, requirements and measures applied by the manufacturer are presented in the Final Report No. 803601413/2012, which is enclosed to this Certificate.

#### Condition of this Certificate use and related information:

1. It applies only to the quality system maintained in the manufacture of above referenced models of medical devices 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 system are changed but until the 9<sup>th</sup> February 2017 at the latest.
3. The Certificate validity is conditioned by positive results of surveillance audits.
4. After fulfilling the relevant EU legislation, the manufacturer shall affix to each medical device, of the above referenced models, the CE-marking followed by the number of the Notified Body according to this example:

**CE 1023**

Issued in Zlín, on 10<sup>th</sup> February 2012



RNDr. Radomír Čevelík

Representative of the Notified Body No. 1023





**Annex to EC Certificate  
No. 12 0102 QS/NB**

Issued for company:

**Nebula Surgical Pvt. Ltd.**

**Registered Office:** B-35/36, Pramukha Swami Arcade, Malaviya Chowk, Dr. Yagnik Road,  
Rajkot - 360 001 Gujarat, India

**List of the medical devices covered by the EC Certificate:**

Type of Implant	Product Name	Size/ Length
Arthroscopic Implant	Tit Top Stop Screw	--
	Tit A.C.L.(Interference) Screw 7 Mm To 9 Mm	20 mm to 40 mm
	Tit Endo Button	--
	Tit Anchor Screw (Corck Screw)	3 mm to 5 mm
	Ligament Stapple U Shape	--
	Umbrella Screws	--
Bone Plates and Screws	1/3 Tubular Plate	3 Hole to 14 Hole
	Small D.C. Plate	3 Hole to 14 Hole
	Small Hook Plate	4 Hole to 14 Hole
	Small L.C.D.C. Plate	4 Hole to 16 Hole
	Ellis Plate	2 Hole to 10 Hole
	Small "T" Plate	2 Hole to 10 Hole
	Oblique "T" Plate	2 Hole to 10 Hole
	Reconstruction Plate 3.5 Mm (Round Hole)	2 Hole to 30 Hole
	Reconstruction Plate 3.5Mm (D.C. Hole)	2 Hole to 30 Hole
	Reconstruction Plate 3.5 Mm (D.C. Hole) Curved	4 Hole to 14 Hole
	Semi Tubular Plate 4.5 Mm	4 Hole to 14 Hole
	Narrow D.C. Plate	4 Hole to 18 Hole
	Narrow L.C.D.C. Plate	4 Hole to 18 Hole
	Broad D.C. Plate	4 Hole to 20 Hole
	Broad L.C.D.C. Plate	4 Hole to 20 Hole
	"T" Buttress Plate	3 Hole to 14 Hole
	"T" Buttress Plate For Humerus	3 Hole to 14 Hole
	"L" Buttress Plate Left & Right	3 Hole to 14 Hole
	Lateral Tibial Plate Left & Right	3 Hole to 16 Hole
	Cobra Plate	4 Hole to 18 Hole
	Cloverleaf Plate	3 Hole to 14 Hole
	Condylar Buttress Plate Left & Right (C.B.P. Plate)	3 Hole to 16 Hole
	Sherman "Y" Plate	2x2x2 to 4x4x10
	Reconstruction Plate 4.5 Mm (Round Hole)	2 Hole to 30 Hole
	Reconstruction Plate 4.5 Mm (D.C.Hole)	2 Hole to 30 Hole
	Reconstruction Plate 4.5 Mm (D.C.Hole) Curved	4 Hole to 12 Hole
	Cortical Screw Hex 3.5 Mm (20 Tpi)	08 mm to 50 mm

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Type of Implant	Product Name	Size/ Length
Bone Plates and Screws	Cortical Screw Hex 3.5 Mm (20 Tpi) (Self Tapping)	08 mm to 50 mm
	Cortical Screw Hex 3.5 Mm (14 Tpi)	08 mm to 50 mm
	Cortical Screw Hex 3.5 Mm (14 Tpi) (Self Tapping)	08 mm to 50 mm
	Cortical Screw Hex 4.5 Mm	10 mm to 80 mm
	Cortical Screw Hex 4.5 Mm (Self Tapping )	10 mm to 80 mm
	Cancellous Screw Hex 4.0 Mm (16 Th.)	10 mm to 85 mm
	Cancellous Screw Hex 4.0 Mm (Fully Th.)	10 mm to 85 mm
	Cancellous Screw Hex 6.5 Mm (16 Th.)	20 mm to 125 mm
	Cancellous Screw Hex 6.5 Mm (32 Th.)	20 mm to 125 mm
	Cancellous Screw Hex 6.5 Mm (Fully Th.)	20 mm to 125 mm
	Malleolar Screw Hex 4.5 Mm	20 mm to 100 mm
Interlocking Nails	I.L. Bolt 2.9 Mm Hex	14 mm to 50 mm
	I.L. Bolt 3.4 Mm Hex	14 mm to 50 mm
	I.L. Bolt 3.9 Mm Hex	14 mm to 70 mm
	I.L. Bolt 4.9 Mm Hex	14 mm to 100 mm
	Harbert Screw	10 mm to 38 mm
	Cap For Humerus Nail	0 to 15 mm
	Interlocking Nail For Humerus Solid (6 Mm To 8 Mm)	18 cm to 30 cm
	Interlocking Nail For Humerus Canulated (7 & 8 M )	18 cm to 30 cm
	Interlocking Nail For Tibia (8 Mm To 11 Mm)	26 cm to 42 cm
	Interlocking Nail For Tibia (Gundrill) (8 Mm To 11 Mm)	26 cm to 42 cm
	Interlocking Nail For Tibia (Crimped) (8 Mm To 11 Mm)	26 cm to 42 cm
	Interlocking Nail For Femur (8 Mm To 13 Mm)	26 cm to 100 cm
	Interlocking Nail For Femur (Gundrill) (8 Mm To 13Mm)	26 cm to 100 cm
	Interlocking Nail For Femur (Crimped) (8 Mm To 13 Mm)	26 cm to 100 cm
	Re-Con Nail Right & Left (9 Mm To 12 Mm)	30 cm to 48 cm
	Re-Con Nail Short (9 Mm To 12 Mm)	22 cm
	K Nail For Femur (6 Mm To 13 M )	26 cm to 100 cm
	V Nail For Tibia (6 Mm To 13 Mm)	26 cm to 42 cm
	Rush Nail (1.5 Mm To 6.0 Mm )	10 cm to 42 cm
	Square Nail For Radius & Ulna (1.5 Mm To 4.0 Mm)	14 cm to 38 cm
	Ender'S Nail (2.0 Mm To 4.5 Mm)	14 cm to 50 cm
	Proximal Bolt 8.0 Mm Hex	50 mm to 125 mm
	Proximal Femoral Nail (P.F.N.)Short (125° ,130°& 135°) 9 Mm To 13 Mm	25 cm

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**Annex to EC Certificate  
No. 12 0102 QS/NB**

Issued for company:

**Nebula Surgical Pvt. Ltd.**

**Registered Office:** B-35/36, Pramukha Swami Arcade, Malaviya Chowk, Dr. Yagnik Road,  
Rajkot - 360 001 Gujarat, India

Type of Implant	Product Name	Size/ Length
Interlocking Nails	Proximal Bolt 6.4 Mm Hex	50 mm to 125 mm
	Proximal Femoral Nail (P.F.N.) Left & Right 9 Mm To 12 Mm	30 cm to 48 cm
	Supra Condylar Nail (I.M.S.C.) - 9 Mm To 13 Mm	15 cm to 44 cm
	Cap For Recon, P.F.N, I.M.S.C.& Cyrus Nail	0, 5, 10, 15 mm
	Cap For Tibia & Femur Nail	0, 5, 10, 15 mm
	Interlocking Nail For Tibia Solid - 8 Mm To 10 Mm	26 cm to 40 cm
	Interlocking Nail For Femur Solid - 9 Mm To 12 Cm	32 cm to 48 cm
	Cyrus Tibia Nail - - 8 Mm To 10 Mm	26 cm to 40 cm
	Cyrus Femur Nail Left & Right 9 Mm To 12 Mm	32 cm to 48 cm
	Tibia Nail High (Upper) Bend -8 Mm To 10 Mm	26 cm to 40 cm
	Trochanteric Femoral Nail (T.F.N.) 130°&135° - 9 Mm To 12 Mm	18 cm
	Elastic Nail - 2.0 Mm To 4.5 Mm	440 mm
Pins	Austin Moore Pin With 2 Nuts	50 mm to 200 mm
Implant For Hip Fixation	CanulatedCancellous Screw Hex (C.C.Screw) 4.0 Mm (16 Thread)	10 mm to 85 mm
	CanulatedCancellous Screw Hex (C.C.Screw) 4.0 Mm Fully Thread	10 mm to 85 mm
	CanulatedCancellous Screw Hex (C.C.Screw) 6.5 Mm & 7.0 Mm (16 Thread)	25 mm to 125 mm
	CanulatedCancellous Screw Hex (C.C.Screw) 8.0 Mm (16 Thread)	25 mm to 140 mm
	CanulatedCancellous Screw Hex (C.C.Screw) 6.5 Mm & 7.0 Mm (32 Thread)	25 mm to 125 mm
	CanulatedCancellous Screw Hex (C.C.Screw) 6.5 Mm & 7.0 Mm (Fully Thread)	25 mm to 125 mm
	Washer For Cancellous / C.C Screw	4.0, 6.5,7.0, 8.0 mm
	D.H.S. Lag Screw (A.O. Type)	50 mm to 120 mm
	D.H.S. Plate Short/Long Barrel (A.O. Type) Round Hole Angle - 120°, 125°, 130°, 135°, 140°, 145°, 150°	2 Hole to 16 Hole
	D.H.S. Plate Short/Long Barrel (A.O. Type) D.C. Hole Angle - 120°, 125°, 130°, 135°, 140°, 145°, 150°	2 Hole to 16 Hole
	Richard D.H.S. Lag Screw (Hex Type)	50 mm to 120 mm
	95° Condylar Blade Plate (A.O. Type) Round Hole (60 Mm To 80 Mm)	3 hole to 16 Hole

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**Registered Office: B-35/36, Pramukha Swami Arcade, Malaviya Chowk, Dr. Yagnik Road,  
Rajkot - 360 001 Gujarat, India**

Type of Implant	Product Name	Size/ Length
Implant For Hip Fixation	95° Condylar Blade Plate (A.O. Type) D.C. Hole (60 Mm To 80 Mm )	3 hole to 16 Hole
	95° D.C.S. Barrel Plate (Round Hole)	4 Hole to 20 Hole
	95° D.C.S. Barrel Plate (D.C.Hole)	4 Hole to 20 Hole
Locking Plate	Small Locking Plate	3 Hole to 14 Hole
	Narrow Locking Plate	4 Hole to 16 Hole
	Broad Locking Plate	4 Hole to 16 Hole
	Reconstruction Locking Plate 3.5 Mm	4 Hole to 16 Hole
	Oblique T Locking Plate (Left & Right)	2 Hole to 10 Hole
	L Buttress Locking Plate (Left & Right)	3 Hole to 14 Hole
	T Buttress Locking Plate	3 Hole to 14 Hole
	Distal Femoral Locking Plate (Left & Right)	4 Hole to 16 Hole
	Proximal Humerus Locking Plate	3 Hole to 8 Hole
	Small T Locking Plate	3 Hole to 10 Hole
	Distal Tibia Metaphesyal Locking Plate	4 Hole to 16 Hole
	Lateral Tibial Locking Plate (Left & Right)	4 Hole to 16 Hole
	Reconstruction Locking Plate 4.5 Mm (D.C.Hole)	4 Hole to 16 Hole
	Richard D.H.S. Short / Long Barrel Locking Plate (125 Degree To 140 Degree)	3 Hole to 14 Hole
	95° D.C.S. Locking Plate	4 Hole to 14 Hole
	1/3 Tubular Locking Plate	4 Hole to 12 Hole
	Distal Tibial Medial Locking Plate (Left & Right)	4 Hole to 14 Hole
	Clavicle Medial Locking Plate (Left & Right)	6 Hole to 8 Hole
	Philos Locking Plate	3 Hole to 14 Hole
	Calcaneal Locking Plate (Left / Right)	Small, Med., Large & Ex. Lar
	Proximal Femur Locking Plate (Left & Right)	3 Hole to 12 Hole
	Superior Anterior Clavical Locking Plate (Left & Right)	6 Hole to 8 Hole
	Distal Medial Humerus Metaphyseal Locking Plate	7 Hole to 15 Hole
	Distal Humerus Dorsolateral Locking Plate (Left & Right)	3 Hole to 12 Hole
	Distal Humerus Dorsolateral With Support Locking Plate (Left & Right)	3 Hole to 12 Hole
	Proximal Tibia Locking Plate (Left & Right)	4 Hole to 16 Hole
	Distal Radius Volar Locking Plate (Left & Right)	2 Hole to 5 Hole
	Anterior Lateral Distal Tibial Locking Plate (Left &	3 Hole to 14 Hole

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Type of Implant	Product Name	Size/ Length
	Right)	
Locking Plate	Proximal Medial Tibial Locking Plate( Left & Right)	4 Hole to 16 Hole
Locking Screws	Locking Screw 3.5 Mm	10 mm to 70 mm
	Locking Screw 4.9 Mm	14 mm to 100 mm
	Locking Cancellous Screw 6.5 Mm (F.Th.)	40 mm to 120 mm
	Locking Cancellous Screw 6.5 Mm (32 Th.)	40 mm to 120 mm
	Locking Cancellous Screw 6.5 Mm (16 Th.)	40 mm to 120 mm
	Locking C. C. Screw 7.3 Mm (F.Th.)	50 mm to 120 mm
	Locking Screw 2.7 Mm	12 mm to 70 mm
	Locking Cancellous Screw 3.5 Mm (16 Th)	16 mm to 75 mm
	Locking Cancellous Screw 3.5 Mm (F.Th.)	16 mm to 75 mm
Mini Plate	Mini Straight Plate ( Without Gap ) 1.5 Mm To 2.5 Mm	02 Hole to 20 Hole
	Mini Straight Plate ( With Gap ) 1.5 Mm To 2.5 Mm	02 Hole to 20 Hole
	Mini "T" Plate -1.5 Mm To 2.5 Mm	2+2 Hole to 3+3 Hole
	Mini "L" Plate ( Left & Right ) 90° 1.5 Mm To 2.5 Mm	2+2 Hole to 3+3 Hole
	Mini "L" (Oblique) Plate ( Left & Right ) 120° - 1.5 Mm To 2.5 Mm	2+2 Hole to 3+3 Hole
	Mini "I" Plate - 1.5 Mm To 2.5 Mm	6 Hole
	Mini "Y" Plate Single & Double - 1.5 Mm To 2.5 Mm	Small, Big & Double
	Mini "X" Plate - 1.5 Mm To 2.5 Mm	4 Hole & 5 Hole
	Mini "Z" Plate ( Left & Right ) - 1.5 Mm To 2.5 Mm	4 Hole
	Mini Curved Plate ( Left & Right ) - 1.5 Mm To 2.5 Mm	4 Hole to 6 Hole
	Mini Angular Plate 150° ( Left & Right ) - 1.5 Mm To 2.5 Mm	4 Hole to 6 Hole
	Mini Orbital Plate With Gap - 1.5 Mm To 2.5 Mm	4 Hole to 6 Hole
	Mini Orbital Plate Without Gap - 1.5 Mm To 2.5 Mm	4 Hole to 6 Hole
	Mini Reconstruction Plate - 1.5 Mm To 2.5 Mm.	2 Hole to 20 Hole
	Mini Nose Plate - 1.5 Mm To 2.5 Mm	H Shape & Y Shape
	Mini 3D Square Plate - 1.5 Mm To 2.5 Mm	2x2 Hole to 4x4 Hole
	Mini Chin Plate - 1.5 Mm To 2.5 Mm	
	Dyanamic Compression Plate (D.C.P.) - 2.7 Mm	4 Hole to 10 Hole
	Mini H Plate - 1.5 Mm To 2.5 Mm	H Shape
	Mini Reconstruction Plate For 2.7 Mm Screw	2 Hole to 24 Hole
	Angle Reconstruction Plate Left & Right - 1.5 Mm To 2.7 Mm	16 Hole to 24 Hole
	T.M.J.Condyle Reconstruction Plate( Left & Right ) -	24 Hole

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Type of Implant	Product Name	Size/ Length
Mini Screws	1.5 Mm To 2.5 Mm	
	Wire Mesh (1.5 Mm, 2.0 Mm)	1x1 to 4x4 Sq. Inch
	Arch Bar	1 Feet
	Mini Screw 1.5 Mm Slot (32 Tpi) - 1.5 Mm To 2.5 Mm	4 mm to 14 mm
	Mini Screw 2.0 Mm Slot (32 Tpi) -1.5 Mm To 2.5 Mm	4 mm to 16 mm
	Mini Screw 2.5 Mm Slot (32 Tpi) - 1.5 Mm To 2.5 Mm	4 mm to 16 mm
	I.M.F. (Intra Maxillary Fixation ) Screw Slot - 1.5 Mm to 2.5 Mm	6 mm to 14 mm
	Mini Screw Hex (24 Tpi) -1.5 Mm To 2.5 Mm	8 mm to 34 mm
Pins & Screws For External Fixator	Steinman Pin (2.5 Mm To 5.0 Mm)	6 Inch to 12 Inch
	Steinman Pin (Trocar Type) (2.5 Mm To 5.0 Mm)	6 Inch to 10 Inch
	S.T.Pin For Distal Device (2.5 To 3.5 Mm)	5 Inch to 8 Inch
	Denham Pin ( 3.0 Mm To 5.0 Mm)	9 inch
	Schanz Screw (2.0 Mm To 5.0 Mm)	3 Inch to 9 Inch
	Schanz Screw (Cancellous Th.) 4.5 Mm To 6.5 Mm	8 Inch to 10 Inch
	Self Drilling Schanz Screw 3.5 Mm To 5.0 Mm	6 Inch to 8 Inch
	Tapper Thread Schanz Screw 5 Mm To 6 Mm	6 Inch to 8 Inch
	Hip Traction Screw - 4.5 To 6.5 Mm	8 Inch to 10 Inch
Ring Fixator	Tension K. Wire (Binet & Trocar Type)	1.5 mm to 2.0 mm
	Olive Wire (Binet& Trocar Type)	1.5 mm to 2.0 mm
Spine Products	Steffi Plate	1 Hole to 6.5 Hole
	Steffi Screws 4.5 & 5.5 Mm	22 mm to 50 mm
	Servical Spinal Plate	5,8,11 Hole
	Hard Sheel Bar	50 mm to 200 mm
	Washer Spike	
	Mono Axial Screw 4.5 Mm	25 mm to 50 mm
	Mono Axial Screw 5.5 Mm	25 mm to 50 mm
	Mono Axial Screw 6.5 Mm	25 mm to 50 mm
	Poly Axial Screw 4.5 Mm	25 mm to 50 mm
	Poly Axial Screw 5.5 Mm	25 mm to 50 mm
	Poly Axial Screw 6.5 Mm	25 mm to 50 mm
	Reduction Screw 4.5 Mm	25 mm to 50 mm
	Reduction Screw 5.5 Mm	25 mm to 50 mm
	Reduction Screw 6.5 Mm	25 mm to 50 mm
	Connection Rod 3.0 Mm	50 mm to 150 mm

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Type of Implant	Product Name	Size/ Length
Spine Products	Connection Rod 5.5 Mm	50 mm to 500 mm
	Tranverse Connector	
	Tit Cervical Spine Plate	21.50 mm to 70 mm
	Tit 4.0 Mm Screw For Cervical Spine Plate	12 mm to 22 mm
	Tit Lock Screw For Cervical Spine Plate	--
	Tit Eco Cage 10 Mm To 18 Mm	10 mm to 100 mm
	Tit Expandable Cage 12 Mm To 18 Mm	20x25mm to 55x75mm
	Tit Tlif Cage (Kidney Cage) 4,8,11 Degree	Height 7 mm to 11 mm
	Tit Plif Cage	20 mm & 25 mm
	Tit Plif Cage (Imported Type) 25 Mm & 30 Mm	Height 8 mm to 12 mm
	Tit Cervical Cage - 12 Mm To 16 Mm	5 mm to 10 mm
	Tit Monoaxial Screw 5 Mm (Double Lock)	25 mm to 50 mm
	Tit Monoaxial Screw 6 Mm (Double Lock)	25 mm to 50 mm
	Tit Polyaxial Screw 5 Mm (Double Lock)	25 mm to 50 mm
	Tit Polyaxial Screw 6 Mm (Double Lock)	25 mm to 50 mm
	Tit Reduction Screw 5 Mm (Double Lock)	25 mm to 50 mm
	Tit Reduction Screw 6 Mm (Double Lock)	25 mm to 50 mm
	Tit Connection Rod 5 Mm	50 mm to 500 mm
	Tit Hooks	All Types
	Tit Spike Washer (Stapples)	
	Tit AntarisStapple - Caudal & Rostal	21 mm to 25 mm
Staples	"U" Type Staples (1.5 Mm To 3.0 Mm)	10 mm to 30 mm
	Coventary Staples	Small, Medium, Large, Ex.Large
Wire	"K" Wire (Double Ended) 0.8 Mm To 3.5 Mm	4 Inch to 18 Inch
	Threaded "K" Wire (Single Side & Double Side) 0.8 Mm To 3.5 Mm	4 Inch to 12 Inch
	"L" Wire (Lambrinudi) 1.5 Mm To 4.5 Mm	20 cm to 50 cm
	S.S. Wire Reel	16 swg to 30 swg
	Dromond Wire	
	Cerclage Wire	0.8 mm to 1.8 mm



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