



Notified Body No 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.
Zlín, Czech Republic – 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 9th 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 10th February 2012



R. Radomír Čevelík

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 Staple 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

Page 2 of 8

Issued in Zlín, on 10th February 2012
Valid until 9th February 2017



m. Pavel Voj

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**

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
	Malleoler 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 HumerusCanulated (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 10 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

Page 3 of 8

Issued in Zlín, on 10th February 2012
Valid until 9th February 2017



Paul Voj
RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023

