



Notified Body No 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.
Zlín, Czech Republic – www.itczlin.cz

EC CERTIFICATE

No. 13 0059 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

Orthopedic Implants – Screws, Plates, Nails

(For detailed specification refer to Annex; pages: 2)

manufactured by company

BIOMED HEALTHTECH Pvt. Ltd.

**Marthanda, 207, 2nd floor, Dr. Annie Besant Road, Worli Naka,
Mumbai - 400 018, Maharashtra, 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. 803601693/2013, 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 the 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 28th January 2018 at the latest.*
3. *The Certificate validity is conditioned by positive results of surveillance audits.*
4. *After fulfilling the relevant EU legislation requirements, 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 29th January 2013



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



Annex to EC Certificate No. 13 0059 QS/NB

Issued for the company:

BIOMED HEALTHTECH Pvt. Ltd.
Marthanda, 207, 2nd floor, Dr. Annie Besant Road, Worli Naka,
Mumbai-400 018, Maharashtra, India

List of the medical devices covered by the EC Certificate:

Product group:	Product name:	Specification (Size):
Screws	Self Tapping	Dia.: 3.5 & 4.5 mm; Length: 16 – 70 mm
	Cortical	Dia.: 3.5 mm; Length: 10 – 40 mm (Diff. 2)
		Dia.: 4.5 mm; Length: 12 – 70 mm (Diff. 2)
	PF	Dia.: 6.5 mm; Length: 16 – 100 mm
		Dia.: 8 mm; Length: 16 – 100 mm
	Cancellous	Short/Full-Thread
		Dia.: 4 mm; Length: 10 – 60 mm (Diff. 5)
		16 mm, 32 mm & Full-Thread
	Cancellous – Cannulated	Short/Full-Thread
		Dia.: 4 mm; Length: 10 – 28 mm (Diff. 2)
Dia.: 4 mm; Length: 30 – 75 mm (Diff. 5)		
Bio-Fixation	16 mm, 32 mm & Full-Thread	
	Dia.: 6.5 mm; Length: 25 – 110 mm (Diff. 5)	
Plates	Bio-Fixation	Short/Full-Thread
	Bio-Fixation Cancellous	Dia.: 4 mm; Length: 10 – 28 mm (Diff. 2)
	Malleolar	Dia.: 4 mm; Length: 30 – 75 mm (Diff. 5)
	DHS / DCS	16 mm, 32 mm & Full-Thread
	Small DCP	Dia.: 6.5 mm; Length: 50 – 120 mm (Diff. 5)
	Reconstruction	Dia.: 3.5 mm / 4.0mm; Length: 10 – 40 mm (Diff. 2)
	1/3 rd Tubular	Dia.: 4.5 mm/ 5.0mm; Length: 12 – 70 mm (Diff. 2)
Semi-Tubular	Dia.: 6.5 mm/ 4.0mm; Length: 25 – 110 mm (Diff. 5)	
Small T	Dia.: 4.5 mm; Length: 25 – 100 mm (Diff. 5)	
T Oblique	Dia.: 12.5 mm; Length: 50 – 110 mm (Diff. 5)	
Narrow DCP	2- 12 Holes	
Broad DCP	3-22 Holes	
DHS Plate (All type)	2 – 12 Holes	
Bio-Fixation Proximal Humerus/ Phillos	2-14 Holes	
	2 – 10 Holes	
	3 – 5 Holes	
	2 – 16 Hole	
	5 – 18 Hole	
	Any size	
	4 – 12 Holes (Diff. 1)	



R. Radomir Čevelík
RNDr. Radomír Čevelík
General Director



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List of the medical devices covered by the EC Certificate:

Plates	Bio-Fixation Small T	4 – 12 Holes (Diff. 1)
	Bio-Fixation T Oblique	3 – 8 Holes (Diff. 1)
	Bio-Fixation Reconstruction	5 – 10 Holes (Diff. 1), 12 – 22 Holes (Diff. 2) Y – Small/Large
	Bio-Fixation Narrow	4 – 12 Holes (Diff. 1); 14 Holes
	Bio-Fixation Broad	4 – 12 Holes (Diff. 1); 14 Holes
	Bio-Fixation/Regular Upper Lateral Tibia / Distal Tibia	3 – 15 Holes Left/Right
	Bio-Fixation/Regular Femoral Condylar/ Distal Femur/ Proximal Femur	3 – 15 Holes
	Bio-Fixation/Regular T Buttress	4 – 12 Holes (Diff. 1)
	Bio-Fixation/Regular L Buttress	Right/Left Leg; 3 – 12 Holes (Diff. 1)
	Cloverleaf	3 – 10 Holes
	Biofixation Plate	Any size
Nails	Tibia	Dia.: 8, 9, & 10 mm; Length: 26 – 44 cms (Diff. 1 cm)
	Compression Tibia	Upper Bend with Dynamic Proximal Hole Dia.: 8, 9, & 10 mm; Length: 26 – 40 cms (Diff. 1 cm)
	Femur	Dia.: 9, 10, 11 & 12 mm; Length: 32 – 48 cms (Diff. 1 cm)
	Recon	Left/Right Dia.: 9, 10, & 11 mm; Length: 34 – 40 cms (Diff. 2 cm)
	PF / TFN	Dia.: 9 mm; Length: any size Dia.: 10 mm; Length: any size Dia.: 11 mm; Length: any size Dia.: 12 mm; Length: any size
	Supracondylar	Dia.: 10, 11, & 12 mm; Length: 18 – 28 cms (Diff. 2 cm)
	Humerus	Dia.: 6.5, 7, & 8 mm; Length: 18 – 28 cms (Diff. 2 cm)



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