

№ 15062

05 EYLÜL 2013



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

## EC CERTIFICATE

No. 12 0428 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 III

### Orthopaedic Implants-Screws, Plates, Nails, Joints, Tumor Prosthesis

(For detailed specification refer to Annex, pages 2-3)

manufactured by company

**XL-Orthomed Pvt. Ltd.**  
Plot No. 8 & 9 Gurukul Industrial  
Corporation Sector 38  
Faridabad-121003, Haryana

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 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 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. 803601465/2012, 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 the above referenced models of the medical devices and it does not substitute the design or type-examination procedures.
2. The Certificate remains valid until the manufacturing conditions or the quality system are changed but until the 26<sup>th</sup> April 2017 at the latest.
3. The Certificate validity is conditioned by positive results of surveillance audits.
4. After receiving of the complementary EC Design-Examination Certificate related to the above referenced models, and fulfilling of 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



*Paul Voj*  
RNDr. Radomír Čevelík

Issued in Zlín, on 27<sup>th</sup> April 2012

Representative of the Notified Body No. 1023

For XL-ORTHOMED (P) LTD

*doel*



*Ab-tif*  
Tercüme Mühendislik  
Danışma Hizmetleri  
Turizm Gıda San. Ve Tic. Ltd. Şti.  
Ceyhan Atuf Kansu Cad.No: 129/2 Bağat/ANKARA  
Tel: 0312 417 79 43 - 472 64 33 Fax: 0312 417 79 48  
Baskent Vergi Dairesi: 011 044 9767

No 15062

05 EYLÜL 2013



Annex to EC Certificate

No. 12 0428 QS/NB

Issued for company:

XL-Orthomed Pvt. Ltd.

Registered site: 622D Shiv Nagar Extn. New Delhi -110058 India

Work site: Plot No. 8 & 9 Gurukul Industrial Corporation Sector 38 Faridabad-121003  
Haryana India

List of the medical devices covered by the EC Certificate:

Product	Range
Hip Prosthesis	Austin Moore Hip Prosthesis
	Thompson Hip Prosthesis
	Bipolar Prosthesis-Fenestrated
	Bipolar Prosthesis Non-fenestrated
	Modular Bipolar prosthesis
	Head portion of Modular bipolar with acetabular cup and head ball
	Total Hip Replacement (THR)
	Femoral Head of THR
	Muller Stem THR
	Long stem THR
	Hip Centralizer THR
	Cement Stopper THR
	THR Stem
	V Stem THR
	THR C-Cup
	C-Bipolar Cup
	Acetabular cup 10 degree angled
Tumoral Prosthesis	Tumoral Hip Spacer
	Tumoral Hip Stem cementing and uncementing
	Tumoral Hip Resection Neck
	Uncementing Hip Stem
	Uncementing Hip Cup
	Tumoral Knee Implants-Spacer

For XL-ORTHOMED (P) LTD.

Authorized Signatory



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RNDr. Radmir Çevelik  
Representative of the Notified Body No. 1023



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List of the medical devices covered by the EC Certificate:

Product	Range
Tumoral Prosthesis	Tumoral Knee Stem-Cementing and Uncementing
	Hing Pin
	Condyle Tumoral distal femur knee along with tibia part rotating platform and static platform
	Knee cement stoper 40 mm
	Condyle Tumoral proximal Tibia knee along with tibia part static platform
	Tumoral Knee along with total hip resection system
	Shoulder head 31 mm to 43 mm Dia
	Shoulder neck
	Shoulder neck, head, stem
	Shoulder cement stopper 40mm
	Elbow prosthesis
	Elbow stem
	Elbow ulna part
	Elbow radius part
Ankle Prosthesis	

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RNDr. Radomir Cevelik  
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