

TGA File Number: 2002/032793

Mr David Sekel  
Portland Orthopaedics Pty Ltd  
Unit 3 / 44 McCauley Street  
MATRAVILLE NSW 2036

Dear Dr Mr Sekel

**Re: CE CERTIFICATES MRA Q00018/01**

Please find enclosed the CE Certificates (Annex II.3 of the Directive 93/42/EEC on Medical Devices) for the recent conformity assessment of the Magron Hip Replacement System.

Three copies of the certificate and attached schedule are provided. In addition a Certificate on buff paper is enclosed to allow easy faxing to your European authorised representative. All Certificates remain the property of the TGA and must be returned to the TGA on demand.

The certificate is issued for Class IIb components only. It is your responsibility to include Class I products in your declaration of conformity.

The recommendation from the certification audit is that the next scheduled surveillance audit be 6 months from the certification audit date. The TGA will contact you closer to the time to fix a suitable date.

You must inform the TGA of any plans of substantial changes to the quality system or the introduction of new products that would extend the scope of the quality system as defined in the Certificate.

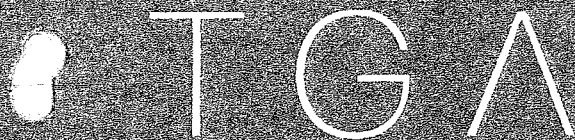
We thank you for working with the TGA in completing the conformity assessment under the MRA.

Yours sincerely

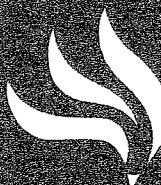


Rod Ferrari  
A/g Manager, Medical Device Assessments  
Conformity Assessment Branch  
20 December 2002

sent 24 December 2002  
BN 1565484



**THERAPEUTIC  
GOODS  
ADMINISTRATION**



Commonwealth Department of  
**Health and  
Ageing**

*Certificate Number: MRA Q00018/01*

*Date of Issue: 20 December 2002*

## **CE CERTIFICATE**

### **FULL QUALITY ASSURANCE SYSTEM APPROVAL CERTIFICATE**

(Annex II, section 3 of the Directive 93/42/EEC on Medical Devices)

*This is to certify that the Full Quality Assurance System described below conforms with the relevant provisions of Annex II, section 3 with the exemption of section 4 of the Council Directive 93/42/EEC on medical devices. Certification is based on an examination of the Full Quality Assurance System which applies at every stage from design to final controls.*

<i>TGA File Number:</i>	2002/032793
<i>Manufacturer Name:</i>	Portland Orthopaedics Pty Ltd
<i>Address:</i>	Unit 3 / 44 McCauley Street MATRAVILLE NSW 2036 Australia
<i>Product Category:</i>	Prosthesis, internal, joint, hip, femoral component (GMDN 35-666)
<i>Product Range:</i>	as per attached schedule
<i>Scope of Quality System:</i>	Design, manufacture and final control of the above product categories
<i>Specific Conditions of Validity:</i>	Nil

*Notified to EC under number <sup>2</sup>*

**CE 0805**

Rita MacLachlan

Director

Conformity Assessment Branch

Therapeutic Goods Administration

PO Box 100

WODEN ACT 2606 AUSTRALIA

<sup>1</sup> This Certificate is valid for the period indicated subject to periodic and satisfactory surveillance.

<sup>2</sup> In compliance with Article 17, CE marking shall be accompanied by our identification number: 0805.



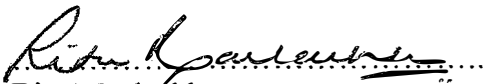
Certificate Number: MRA Q00018/01  
Date of Issue: 20 December 2002

## CE CERTIFICATE

### SCHEDULE OF PRODUCTS

#### PRODUCTS:

Magron Primary Stem (various)  
Magron Revision Stem (various)  
Magron Revision Stem with Suture Holes (various)  
Magron Neck (various)  
Magron Hybrid Neck (various)  
Magron Extension Module Standard (various)  
Magron Extension Module Hybrid (various)

  
Rita MacLachlan  
Director  
Conformity Assessment Branch  
Therapeutic Goods Administration  
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