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TGA THERAPEUTIC GOODS ADMINISTRATION

PO Box 100, WODEN, ACT 2606, Australia
Telephone (02) 6232 8704 Facsimile (02) 6232 8785

Commonwealth Department of Health and Ageing

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

TGA 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.

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

Notified to EC under number [2]

CE 0805

Rita Maclachlan
Director
Conformity Assessment Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606 AUSTRALIA

[1] *This Certificate is valid for the period indicated subject to periodic and satisfactory surveillance.*
[2] *In compliance with Article 17, CE marking shall be accompanied by our identification number: 0805.*

This Certificate is the property of the Therapeutic Goods Administration and must be returned upon demand

TGA THERAPEUTIC GOODS ADMINISTRATION

AUSTRALIA

Health and Ageing

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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
PO Box 100
WODEN ACT 2606 AUSTRALIA

[1] *This Certificate is valid from the date of issue subject to periodic and satisfactory surveillance.*