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**Australian Government**  
**Department of Health and Ageing**  
**Therapeutic Goods Administration**

06 September 2006

TGA File Number: 2005/072598  
Submission ID: DV-2005-4494

Portland Orthopaedics Limited  
Unit 3, 44 McCauley St  
MATRAVILLE NSW 2036

Attention: Ronnie Eshel

CONFORMITY ASSESSMENT CERTIFICATE AU Q00042/01 + schedule of suppliers  
MRA EC CERTIFICATE MRA Q00035/01 + schedule of suppliers

Please find enclosed the Conformity Assessment Certificate under Schedule 3 – Part 1 of the *Therapeutic Goods (Medical Devices) Regulations 2002* and the respective EC certificate under the Australia – EU MRA.

One copy of the Conformity Assessment Certificate and two copies of the MRA certificates are enclosed. All certificates remains the property of the TGA and must be returned to the TGA on demand.

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 certificates.

Please note: because the MRA EC certificate is, in general terms, subject to the currency of the conformity assessment certificate, the expiry date in the MRA CE certificate has been aligned with that in the conformity assessment certificate.

The schedule of suppliers for the conformity assessment certificate will be updated at a later stage.

Yours sincerely

A handwritten signature in black ink that reads "Rod Ferrari".

Rod Ferrari  
Medical Device Assessments Section  
Office of Devices, Blood and Tissues

*Certificate Number: AU Q00042/01*

## **CONFORMITY ASSESSMENT CERTIFICATE**

### **FULL QUALITY ASSURANCE PROCEDURES**

Schedule 3 – Part 1 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (Australia)

This is to certify that the quality management system described below complies with the relevant provisions of Schedule 3 – Part 1, excluding clause 1.6, of the *Therapeutic Goods (Medical Devices) Regulations 2002*. Certification is based on an assessment of the Full Quality Management System, applied at each stage of medical device manufacture, from the design of a device until its final inspection before being supplied.

**TGA File Number:** 2005/072598

**Manufacturer Name:** Portland Orthopaedics Limited

**Address:** Unit 3 44 McCaulley Street  
MATRAVILLE NSW 2036  
Australia

**Facility:** As above

**Suppliers:** as per schedule of suppliers

**Scope of the certification:** prosthesis, hip, internal, femoral component  
[GMDN 35666]

prosthesis, hip, internal, acetabular component  
[GMDN 35661]

**Automatic Conditions:** apply under section 41EJ of the *Therapeutic Goods Act 1989*

**Additional Conditions:** NIL

**Commencement date:** 7 November 2005  
**Re-Issue date:** 7 November 2010  
**Expiry date:** 7 November 2010

This certificate is valid from the commencement date, subject to ongoing compliance, and unless it has been restricted, suspended, revoked or is no longer in effect.

*Shelley Tang*  
 Shelley Tang  
 Head, Medical Devices Assessment Section  
 Office of Devices, Blood and Tissues  
 Therapeutic Goods Administration  
 PO Box 100  
 WODEN ACT 2606 AUSTRALIA

*This Certificate is the property of the Therapeutic Goods Administration and must be returned upon demand*  
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Certificate Number: AUQ00042

Schedule Date of Issue: 7 November 2005

Schedule Date of Reissue:

## Conformity Assessment Certificate – Schedule of Suppliers

For Portland Orthopaedics Limited

HTV Unit 3 9-11 Cullen Place SMITHFIELD NSW 2164	testing of machined parts
United Surface Technologies 26-32 Aberdeen Rd ALTONA VIC 3018	coating
Molten Splat Pty Ltd 55 Gissing Street BLACKBURN SOUTH VIC 3130	testing of coating
Engelhard Corporation Inc. 12 Thompson Road EAST WINDSOR CT United States of America	plasma spray coating
Ceram Tech AG Fabrikstrasse 23-29 D-73207 PLOCHINGEN Germany	production of ceramic liners
MediTech 2710 American Way FORT WAYNE IN 46809 United States of America	polyethylene inserts
ASDM Pty Ltd 80 Bellingara Road MIRANDA NSW 2228	bone screws
Steritech Limited 5 Widemere Road WHETHERIL PARK NSW 2164	sterilisation
Ams Laboratories 118 Hattersley Street ROCKDALE NSW 2216	microbiological testing

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