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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 remain 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, appearing to read '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:

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

Certificate Number: AU Q00042

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 State 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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