

# PORLAND ORTHOPAEDICS PTY LTD

A.C.N. 086 839 992

101

Suite 3 Level 5  
St George Private Hospital  
1 South Street  
Kogarah NSW 2217

Tel: +61 2 9588 2121  
Fax: +61 2 9587 1014

Company  
File on  Licence  
 Inspection  
 Auto Response  
 Auditor... *Dr. David Buckley*  
*A. Duff.*

Mr Robert W. Tribe  
GMP Auditor  
PO Box 100  
Woden ACT 2606

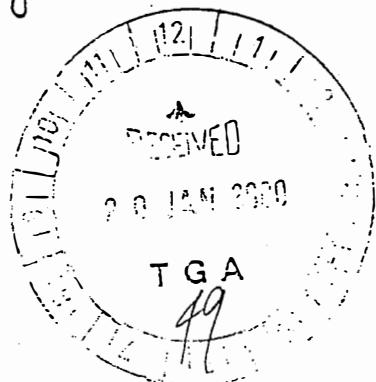
*copy K. Smith.*

18<sup>th</sup> January, 2000

→ *L. Ellerbeck*

*Any action.*

*Alm  
24/1/99.*



Dear Mr Tribe,

Re: Single step manufacture (release for supply) audit at Portland Square Pty Ltd 28<sup>th</sup> January 2000.

Further to discussion with Mr David Buckley on 17/1/00 I am writing to inform you of present restructuring at the Portland group and to request postponement or possible incorporation of the above audit into planned TGA audits for CE Mark.

Portland Square Pty Ltd now provides licence to Portland Orthopaedics Pty Ltd to manufacture and release The Margron Hip Replacement System for supply. Based on this variation I would expect the TGA licence would require a name change to Portland Orthopaedics Pty Ltd.

Furthermore, Portland Orthopaedics is currently in the process of completing EN 46002/ISO 9002 and CE Mark administration with completion expected by February – March 2000. As part of the Mutual Recognition Agreement the TGA will be conducting full system audits including Release for Supply by way of granting CE Mark approval.

Therefore, in order to minimise audit costs we would request that the full system and product audit for CE Mark would also satisfy the requirements of the scheduled TGA licence audit.

I understand that David Buckley will also bring this matter to your attention, I look forward to hearing from you in due course.

Yours sincerely,

*A. Duff*

*RS* Dr Ron Sekel  
Managing Director