Rodolfo Ferrari
07/11/2005 11:21 AM

To: r.eshel@portland-orthopaedics.com
cc: Cathie Stoffell/TGA/Health@Health_gov_au
Subject: TGA- Conformity Assessment Certificates

7 November 2005
Submission ID: DV-2005-4494

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

Attention: Ronnie Eshel

RE: CONFORMITY ASSESSMENT CERTIFICATE
CERTIFICATE: AU Q00042/01 + schedule of suppliers

Please find enclosed the Conformity Assessment Certificate under Schedule 3 – Part 1 of the *Therapeutic Goods (Medical Devices) Regulations 2002*. An electronic copy is sent to you by electronic mail.

The enclosed Australian conformity assessment certificate enables you to make online applications with the TGA via https://www.tgasime.health.gov.au/SIME/home.nsf to include medical devices on the Australian Register of Therapeutic Goods.

Please lodge the two certificates under Manufacturer Evidence without delay.
I would appreciate you to contact Cathie.Stoffell@health.gov.au for assistance.

CONDITIONS

The enclosed conformity assessment certificates are issued on the understanding that:

- the products are designed and manufactured under Portland's quality management system which was assessed by the TGA at the time of MRA CE certification (certificate MRA Q00018/01) and that the system is current.

- Portland has conducted the prescribed conformity assessment procedure for the products (Schedule 3 Part 1) and has evidence to demonstrate that the products comply with all applicable Essential Principles.

Portland shall sign (but not submit) a Declaration of Conformity as required by Part 1 before the products are included in the ARTG.

An extended MRA CE certificate including the additional GMDN code is not included at this stage and its issue will be subject to the results of the coming surveillance audit.

Please note that should the coming surveillance audit result in major non conformities of a critical nature, the TGA may suspend the enclosed certification until these are satisfactorily

rectified.

NOTE: Should you hold a current TGA Manufacturer Licence for your premises and this Conformity Assessment Certificate covers all medical devices included under the scope of the existing licence and once you "include" the said devices in the ARTG, you may be able to cancel your licence. If there are products under your existing licence which will not be included in the ARTG under the issued certificate or if you manufacture or process products for a third party under the existing licence you are required to continue the current licence arrangements.

Yours sincerely

Rod Ferrari
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