

Certificate Number: AU DE00007/01

CONFORMITY ASSESSMENT CERTIFICATE DESIGN EXAMINATION

Schedule 3 – Part 1.6 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (Australia)

This is to certify that the design of the device(s) below complies with the relevant provisions of Schedule 3 – Part 1.6 of the *Therapeutic Goods (Medical Devices) Regulations 2002*. Certification is based on examination of the evidence of conformity to the Essential Principles.

TGA File Number: 2003/003664 2004/009021 2004/052953
2004/052955 2004/052956 2004/052957

Manufacturer Name: Poly Implants Protheses
Address: 337 Avenue de Bruxelles
83507 LA SEYNE-SUR-MER, Cedex
France

Facility: Allée Jean Giono
83140 Six Fours Les Plagues
France

Scope of the certification: Prosthesis, mammary, internal, gel filled
[GMDN~~X~~6197]
Models: IMGHC-LS-S; IMGHC-LS-H;
IMGHC-LS-EH; IMGHC-TX-S; IMGHC-TX-H;
IMGHC-TX-R; IMGHC-TX-AL; IMGHC-TX-AR;
IMGHC-TX-EH

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

Additional Conditions: NIL

Commencement date: 18 October 2004

Re-Issue date:

Expiry date: 18 October 2009

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from the commencement date, subject to ongoing compliance, and unless it has been restricted, suspended, revoked or is no longer in effect.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
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This Certificate is the property of the Therapeutic Goods Administration and must be returned upon demand
C-CA1.6

