



Certificate Number: AU Q00018/01

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.

Commonwealth Department of
**Health and
Ageing**

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

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

Facility: Allee Jean Giono
83140 Six Fours Les Plagues
France

Suppliers: MXM Laboratories
220 Chemin Saint Bernard
06224 Vallauris Cedex
France

Scope of the certification: Prosthesis, mammary, internal, gel filled
[GMDN 6197]

apply under section 41-EJ 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from the commencement date, subject to ongoing compliance, and unless it has been restricted, suspended, revoked or is no longer in effect.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
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