

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.

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: 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, ³mammary, internal, gel filled
[GMDN ~~X~~6197]

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from the commencement date, subject to ongoing compliance, and unless it has been restricted, suspended, revoked or is no longer in effect.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