

Certificate Number: AU Q00050/01

CONFORMITY ASSESSMENT CERTIFICATE
FULL QUALITY ASSURANCE PROCEDURESSchedule 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: 2006/000515

Manufacturer Name: IMAXEON PTY LTD

Address: Unit 1, 38-46 South Street
RYDALMERE NSW 2116
Australia

Facility: as above

Suppliers: as per attached schedule of suppliers

Scope of the certification: Contrast Medium Injector System, powered, multiphase [GMDN 40723]
Syringe, hypodermic, metered-delivery [GMDN 35904]

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

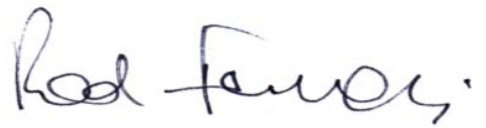
Additional Conditions: NIL

Commencement date: 27 February 2006

Re-Issue date:

Expiry date: 27 February 2011

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from the commencement date, subject to ongoing compliance, and unless it has been restricted, suspended, revoked or is no longer in effect.



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