



**Australian Government**  
**Department of Health and Ageing**  
**Therapeutic Goods Administration**

*Certificate Number: AU Q00217/01*

**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:** 2008/004115

**Manufacturer Name:** Haemologic Biotech Pty Ltd

**Address:** D2 / 15 Narabang Way  
Belrose, NSW 2085  
Australia

**Facility:** As above

**Suppliers:** As per attached Schedule of Suppliers

**Scope of the certification:** Blood collection/cell-culture container [GMDN 44904]

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

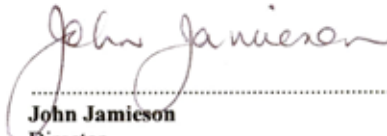
**Additional Conditions:** NIL

**Commencement Date:** 23 March 2009

**Re-issue date:**

**Expiry date:** 23 March 2014

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from the commencement date, subject to ongoing compliance, and unless it has been restricted, suspended, revoked or is no longer in effect.



**John Jamieson**  
Director,  
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Office of Devices, Blood and Tissues  
Therapeutic Goods Administration  
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WODEN ACT 2606 AUSTRALIA

*This Certificate is the property of the Therapeutic Goods Administration and must be returned upon demand*  
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