



**Australian Government**

**Department of Health**  
Therapeutic Goods Administration

## Quality Management System Certificate

### ISO 13485:2016

**Certificate Number:**

MI-2018-CE-02307-2

**Issued to:**

Haemologic Biotech Pty Ltd

This is to certify that the Quality Management System for the design, development and manufacture of the devices described below conforms to the relevant provisions of ISO 13485: 2016 (not including clauses 7.5.3, 7.5.4, 7.5.2, 7.5.9.2, 7.10 and parts of clauses 4.1.6, 6.3 and 7.6 relating to software validation).

**TGA File Number:** 2014/028697

**Manufacturer Name:** Haemologic Biotech Pty Ltd

**Manufacturer Address:** D2 & D3/15 Narabang Way  
Belrose NSW 2085  
AUSTRALIA

**Scope of Certification:** The design and development, manufacture, final inspection and product release of the following medical device categories:

- Blood collection devices
- Cell culture containers
- Tubing (nebuliser set, low pressure compressor gas)
- Air/oxygen masks and accessories
- Non heated nebulisers
- Syringes (including self-loading)
- IV infusion tubing set products

**Special conditions:** Implementation of Plasma bags EtO sterilisation validation.

**Effective Date: 29 October 2021**

**Expiry Date: 21 January 2024**

Name and Signature of an authorised person of the Competent Authority of Australia

**Hon. Prof. Dr Jorge E. Garcia**  
Director, Quality Audits and Assessments Section,  
Medical Devices Surveillance Branch

This certificate is only valid for the period indicated, subject to periodic and satisfactory surveillance audits.

This Certificate remains the property of the Therapeutic Goods Administration and must be return upon demand.  
The authenticity of this Certificate may be verified with the Therapeutic Goods Administration as the issuing authority.

PO Box 100 Woden ACT 2606 ABN 40 939 406 804  
Phone: 02 6232 8644 Fax: 02 6203 1605 Email: [info@tga.gov.au](mailto:info@tga.gov.au) [www.tga.gov.au](http://www.tga.gov.au)

**TGA** Health Safety  
Regulation