

10 Appendix A

Quality Policy

Haemokinesis Pty Ltd is committed to design, develop, manufacture and distribute medical devices which are safe and effective and will strive to continue producing medical devices that consistently meet the needs and expectations/requirements of the medical device industry.

The organization is committed to implementing and maintaining an effective quality management system in accordance with ISO 9001, ISO 13485 and ensure compliance with Directive 98/79/EC and the Therapeutic Goods (Medical Devices) Regulations 2002.

Quality Assurance provides assurance of satisfactory product quality as a result of meeting specifications, testing requirements and sampling. The organization requires this before products are supplied to the customer.

Haemokinesis personnel are continually educated in the importance of quality in their daily activities and understand that quality is everyone's responsibility. We continually strive to achieve the highest standard for quality in all aspects of the company.

AUTHORIZED BY:

Jim Manolios
Chief Executive Officer

Jim Manolios

Signature

23rd May 2018

Date