

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Genea Biomedx Pty Ltd
Level 2, 321 Kent Street
Sydney
New South Wales
2000
Australia

Holds Certificate Number:

MD 630526

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, development and manufacture of IVF media incorporating antibiotics and human serum albumin and the control of manufacture of embryo incubators, vitrifiers and sterile consumables for IVF procedures.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2015-05-27

Latest Revision Date: 2021-05-11

Effective Date: 2021-05-27

Expiry Date: 2024-05-26

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