



Certificate of Registration

OUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Cytocell Limited Oxford Gene Technology 418 Cambridge Science Park Milton Road Cambridge CB4 0PZ United Kingdom

Facility ID Number: F005143

Holds Certificate No:

MDSAP 736531

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure Brazil: RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009 Canada: Medical Devices Regulations - Part 1 - SOR 98/282 Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

> Design, development and manufacture of DNA FISH probes, ancillary products and in vitro diagnostic kits and reagents for the detection of chromosomal abnormalities in life science research and diagnostic use.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2019-09-18

Effective Date: 2022-09-16

Expiry Date: 2025-09-15

Page: 1 of 1



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This certificate remains the property of BSI and shall be returned immediately upon request. An electronic certificate can be authenticated online. Printed copies can be validated at www.bsigroup.com/ClientDirectory To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA A Member of the BSI Group of Companies.