By Royal Charter

Certificate of Registration

QUALITY 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

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM
BSI Group America Inc. is an MDSAP recognised auditing organization

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