bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

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

Facility ID Number: F003690

Holds Certificate No: **MDSAP 736531**

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Brasil - 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.

This certificate is traceable to this company's original registration certificate number 10228546 dated September 18, 2019 and issued by LRQA

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2019-09-18 Effective Date: 2021-03-02 Expiry Date: 2022-09-15

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

...making excellence a habit.™