Certificate of Approval

This is to certify that the Management System of:

Cytocell Ltd

418 Cambridge Science Park, Milton Road, Cambridge, CB4 0PZ, United Kingdom
MDSAP Facility Identifier: F003690

has been audited by Lloyd's Register Quality Assurance and found to conform to the following audit criteria:

ISO 13485:2016

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

United States:

21 CFR 803
21 CFR 806
21 CFR 807 – Subparts A to D
21 CFR 820

Cliff Muckleroy- Area Operations Manager Americas
Issued by: Lloyd's Register Quality Assurance, Inc.

Certificate approval number: LRQ0960610
Effective date: 2019 September 18
Expiry date: 2022 September 15
Certificate issue number: 10228546

Original approval:
MDSAP/ISO 13485 – 2019 September 18

Approval Number: MDSAP – 00022147

The scope of this approval is applicable to:

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.

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Lloyd's Register Quality Assurance, Inc. is an MDSAP authorised auditing organization.