

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. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021

Canada: Medical Devices Regulations - Part 1 - SOR 98/282

Japan: MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act

USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Design, development and manufacture of in vitro diagnostic kits and reagents for the detection of chromosomal abnormalities.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2019-09-18

Effective Date: 2023-11-21

Expiry Date: 2025-09-15



BSI Group America Inc. is an MDSAP recognised auditing organization