

Our ref: IVDR 747622

Date: 2023-08-30

To whom it may concern,

This letter confirms that BSI, an EU Notified Body (EU designation No.2797), has issued EU Quality Management System Certificate No. IVDR 747622 R000 under the In Vitro Diagnostics Regulation (EU) 2017/746 to the medical device manufacturer:

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

With the following scope:

Device Schedule: Class C devices

Class C devices	Intended purpose
W0106 – Genetic testing	Chromosomal analysis device for the detection of prenatal trisomy 13 & 21.
IVP3004 – In vitro diagnostic Devices which require knowledge of chromosomal analysis	
W0106 – Genetic testing	Chromosomal analysis devices for the detection of acquired cancer-related chromosome alterations.
IVP3004 – In vitro diagnostic Devices which require knowledge of chromosomal analysis	

This Certificate was first issued on 9th March 2023, it is current and valid until 8th March 2028.

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BSI performs annual surveillance audits of the manufacturer's quality management system according to the concerned In Vitro Diagnostics Regulation (EU) 2017/746 requirements. The last audit report issued to Cytocell Limited is dated 28th July 2023.

BSI confirms that the products listed in Attachment 1 are covered under IVDR 747622.

The information disclosed under this letter is provided pursuant to express request of Cytocell Limited and is subject to obligations of confidentiality between BSI and Cytocell Limited and of recipient and Cytocell Limited.

BSI confirms that its conditions of contract require Cytocell Limited to notify the Notified Body about incidents and field safety corrective actions.

Yours sincerely,

Ana Chiva

Digitally signed
by Ana Chiva
Date:
2023.08.30
07:30:07 +02'00'

Ana Chiva
Scheme Manager



Attachment 1:

W0106 – Genetic testing		
IVP3004 – In vitro diagnostic Devices which require knowledge of chromosomal analysis		
Product name	Part number	Intended purpose
Prenatal 13 and 21 Enumeration Probe kit (10 / 5 tests)	CE-LPA 003 / CE-LPA 003-S	Chromosomal analysis device for the detection of prenatal trisomy 13 & 21.

W0106 – Genetic testing		
IVP3004 – In vitro diagnostic Devices which require knowledge of chromosomal analysis		
Product name	Part number	Intended purpose
BCR/ABL (ABL1) Translocation, Dual Fusion Probe (10 / 5 tests)	CE-LPH 007 / CE-LPH 007-S	Chromosomal analysis devices for the detection of acquired cancer-related chromosome alterations.
ATM Deletion Probe (10 / 5 tests)	CE-LPH 011 / CE-LPH 011-S	
MLL (KMT2A) Breakapart Probe (10 / 5 tests)	CE-LPH 013 / CE-LPH 013-S	
AML1/ETO (RUNX1/RUNX1T1) Translocation, Dual Fusion Probe (10 / 5 tests)	CE-LPH 026 / CE-LPH 026-S	
AML1 (RUNX1) Breakapart Probe (10 / 5 tests)	CE-LPH 027 / CE-LPH 027-S	
CKS1B/CDKN2C (P18) Amplification/Deletion Probe (10 / 5 tests)	CE-LPH 039 / CE-LPH 039-S	
FAST PML/RAR α (RARA) Translocation, Dual Fusion Probe (10 / 5 tests)	CE-LPH 064 / CE-LPH 064-S	
IGH/MAF Plus v2 Translocation, Dual Fusion Probe (10 / 5 tests)	CE-LPH 108 / CE-LPH 108-S	
BCR/ABL (ABL1) Plus Translocation, Dual Fusion Probe (10 / 5 tests)	CE-LPH 038 / CE-LPH 038-S	
CBFB Breakapart Probe (10 / 5 tests)	CE-LPH 089 / CE-LPH 089-S	