By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/746, Annex IX Chapter I and III

IVDR 747622 R000

Manufacturer: Cytocell Limited

Address:
Oxford Gene Technology
418 Cambridge Science Park
Milton Road
Cambridge
CB4 0PZ
United Kingdom

Single Registration Number: GB-MF-000016893

EU Authorised Representative: Sysmex Europe SE

Address:
Deelböge 19 D
22297 Hamburg
Germany

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/746, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class D devices, and self-test, near-patient test and companion diagnostic devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2023-03-09**

Current Issue Date: **2025-08-29**

Starting Validity Date: **2025-08-29**

Expiry Date: **2028-03-08**

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Device Schedule: Class C devices

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

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2023-03-09	3413836	Issued
Current	30517027	Amended – Change of EU Authorised Representative address.

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

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