

# 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

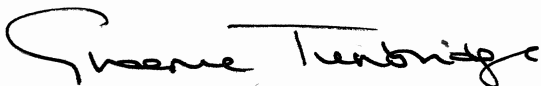
**Address:**

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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Page 1 of 3

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.

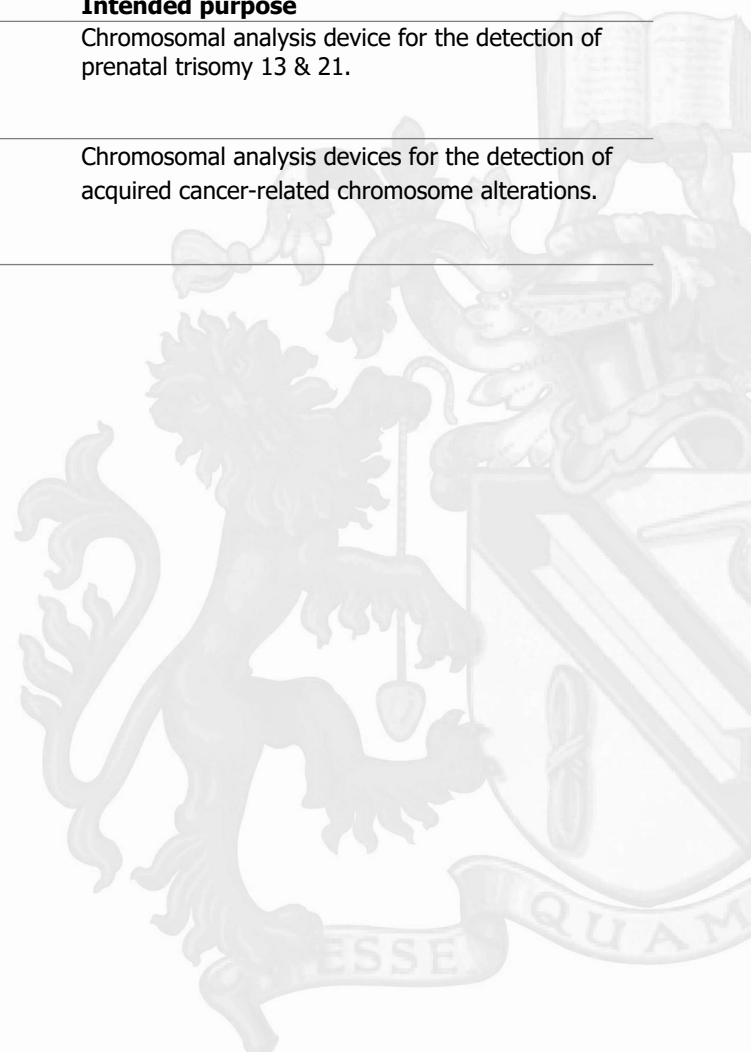
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### Device Schedule: Class C devices

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



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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](mailto: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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NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80  
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at Seventh and Eighth Floors, The Acre, 90 Long Acre, London, WC2E 9RA, UK.  
A Member of the BSI Group of Companies.