By Royal Charter

# EU Quality Management System Certificate

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

## IVDR 752178 R000

**Manufacturer:** Invivoscribe Inc

**Address:**
10222 Barnes Canyon Rd
Bldg. 1
San Diego
California
92121
USA

**Single Registration Number:** US-MF-000011736

**EU Authorised Representative:** Invivoscribe Technologies, SARL

**Address:**
c/o Ficorec Domiciliation Services
132, Boulevard Michelet
Hall Nord - 5ème étage
13008 Marseille
France

**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: **2023-05-07**

Current Issue Date: **2025-11-28**

Starting Validity Date: **2025-11-28**

Expiry Date: **2028-05-06**

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### Device Schedule: Class D, C and B devices

| **Class C companion diagnostic devices** | **Intended purpose** |
|---|---|
| LeukoStrat® CDx FLT3 Mutation Assay | See IVDR 752181 |
| **Class C devices** | **Intended purpose** |
| W0106 - Genetic Testing<br>IVP 3011 - In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS) | In vitro diagnostic polymerase chain reaction (PCR) devices, including software, intended to assist in the diagnosis of hematologic malignancies |

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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 |
|---|---|---|
| 2023-05-07 | 3477594 | Issued |
| 2024-03-04 | 30028492 | Amended - EU Authorised Representative address updated. |
| Current | 30545530 | Supplemented - Addition of device group Class C W0106 + IVP 3011. |

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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.

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.

invivoscribe®
Improving Lives with Precision Diagnostics®
+1 858.224.6600 Fax +1 858.224.6601
support@invivoscribe.com

June 2026

# Scope of EU Quality Management System Certificate

**Companion to EU Quality Management System Certificate (IVDR 2017/746, Annex IX, Chapters I and III)**

Certificate Reference: **IVDR 752178 R000**
Single Registration Number (SRN): **US-MF-000011736**
Notified Body: **BSI Group The Netherlands B.V.**

**Purpose**
This letter is provided to clarify the specific products covered under the scope of the above-referenced EU Quality Management System Certificate, as the certificate does not explicitly list individual catalog numbers or product names.

**Scope**
The certified device classification includes:

- **Class C Devices**
- **W0106 – Genetic Testing / IVP 3011**
- *In vitro* diagnostic devices requiring knowledge of molecular biology techniques, including nucleic acid amplification methods and next-generation sequencing (NGS)

**Covered Product(s)**
The following product(s) are included within the scope of the certified quality management system:

| Catalog No. | Product Name | Manufacturer |
|---|---|---|
| K4120431 | LeukoStrat® CDx *FLT3* Mutation Assay | Invivoscribe, Inc<br>10222 Barnes Canyon Road, Building 1,<br>San Diego, CA USA 92121 |
| 91010101 | IdentiClone® Dx *IGH* Assay | |

**Statement of Applicability**
The above-listed product is designed, manufactured, and controlled under the certified Quality Management System assessed and approved by BSI Group The Netherlands B.V. in accordance with Regulation (EU) 2017/746 (IVDR), Annex IX, Chapters I and III.

This Letter should be read in conjunction with the EU Quality Management System Certificate referenced above.