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 Medical Devices

First Issue Date: **2023-05-07**

Current Issue Date: **2024-03-04**

Starting Validity Date: **2024-03-04**

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

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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
Current	30028492	Amended- EU Authorised Representative address updated.

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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 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.