EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 752181 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 assessment of the technical documentation in accordance with Regulation (EU) 2017/746, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III 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: **2024-10-01**

Starting Validity Date: **2024-10-01**

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

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Device Schedule:

Intended Purpose as per the Instructions for Use:

The LeukoStrat CDx FLT3 Mutation Assay is a PCR-based in vitro diagnostic test designed to detect internal tandem duplication (ITD) and tyrosine kinase domain (TKD) mutations D835 and I836 in the FLT3 gene in genomic DNA extracted from mononuclear cells obtained from peripheral blood or bone marrow aspirates of patients diagnosed with acute myelogenous leukemia (AML). The LeukoStrat CDx FLT3 Mutation Assay may be used as a companion diagnostic for the following therapeutic:

In regions where XOSPATA® (gilteritinib fumarate) is available, the LeukoStrat CDx FLT3 Mutation Assay is used as an aid in the assessment of patients with AML for whom XOSPATA® (gilteritinib fumarate) treatment is being considered.

In regions where VANFLYTA® (quizartinib hydrochloride) is available, the LeukoStrat® CDx FLT3 Mutation Assay is used as an aid in the assessment of patients with FLT3-ITD+ AML for whom VANFLYTA® (quizartinib hydrochloride) treatment is being considered.

The qualitative, non-automated test is for use on the 3500xL or 3500xL Dx Genetic Analyzers.

Risk Classification: Class C Companion Diagnostic

Basic UDI-DI: 081002273K41204314J

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)
LeukoStrat CDx FLT3 Mutation Assay	K4120431	IVR 0302

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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	3477596	Issued.
2024-03-04	30029831	Amended - EU Authorised Representative address updated.
Current	30001283	Supplemented - Addition of companion diagnostic claim for VANFLYTA® (quizartinib hydrochloride).

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