DECLARATION OF CONFORMITY

Manufacturer:	Invivoscribe, Inc. 10222 Barnes Canyon Rd. Bldg. 1 San Diego, CA 92121	
	SRN: US-MF-000011736	
Authorized Representative:	Invivoscribe Technologies, SARL c/o Ficorec Domiciliation Services 132, Boulevard Michelet Hall Nord – 5ème étage 13008 Marseille France +33 (0)4 42 01 78 10	
	SRN: FR-AR-000003774	
Device:	Trade Name:	LeukoStrat® CDx *FLT3* Mutation Assay
	Device Name:	LeukoStrat® CDx *FLT3* Mutation Assay
	Catalog #:	K4120431
	Intended Purpose:	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. The qualitative, non-automated test is for use on the 3500xL or 3500xL Dx Genetic Analyzers.
	Device Code:	W01060299
	Basic UDI-DI:	081002273K41204314J
	Risk Classification:	Class C, Companion Diagnostic
Common Specifications (CS):	N/A	
Notified Body:	Name:	BSI
	Identification #:	2797
	Conformity assessment	Annex IX from EU 2017/746

	procedures performed:	
	Certification(s) Issued:	• IVDR QMS Certificate: IVDR 752178 • Technical Documentation Assessment Certificate (Annex IX Chapter II): LeukoStrat® CDx *FLT3* Mutation Assay - IVDR 752181
European Union Declaration of Conformity:	This EU Declaration of Conformity is issued with the sole responsibility of Invivoscribe, Inc. I, the undersigned, hereby declare that the *in-vitro* diagnostic medical devices specified above conform to the EU 2017/746, *In vitro* Diagnostic Regulation.	

Date of Validity: 02 Oct 2023

By: Jason Gerhold

Jason Gerhold
Global Director of Regulatory, Quality & Clinical Affairs
Invivoscribe Inc.
10222 Barnes Canyon Rd. Bldg 1
San Diego, California 92121
USA