



## DECLARATION OF CONFORMITY

**Manufacturer:** **Invivoscribe Inc.**  
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United States of America

**Authorized Representative:** **Invivoscribe Technologies, SARL**  
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**Family Name:** LeukoStrat®

**Device Trade Name:** **CDx FLT3 Mutation Assay**

Catalog #	Device	Description
K4120151	LeukoStrat® CDx FLT3 Mutation Assay	Internal Use Kit
K4120291	LeukoStrat® CDx FLT3 Mutation Assay	Distributed Kit

I, the undersigned, hereby declare that the *in-vitro* diagnostic medical devices specified above conform to the European Directive 98/79/EC, *In vitro* Diagnostic Medical Device Directive, Annex III.

Date of Validity: 20 Mar 2019

By: Jason Gerhold

Jason Gerhold  
Global Director of Regulatory Affairs & Quality Assurance  
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