



## DECLARATION OF CONFORMITY

**Manufacturer:** Invivoscribe, Inc.  
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**Family Name:** IdentiClone™

**Device Trade Name:** IGK Gene Clonality Assay

Catalog #	Device	Quantity	Basic UDI-DI	GTIN
9-102-0021	IGK Gene Clonality Assay for ABI Fluorescence Detection	33 Reactions	08100227391020021PM	00850052003173
9-102-0031	IGK Gene Clonality Assay MegaKit for ABI Fluorescence Detection	330 Reactions	08100227391020031PQ	00850052003203

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: 17 May 2022

By: 

Jason Gerhold  
Global Director of Quality, Regulatory and Clinical Affairs  
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