invivoscribe

DECLARATION OF CONFORMITY

Manufacturer:

Invivoscribe, Inc.
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Authorized Representative:

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Family Name: IdentiClone™

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

Catalog #	Device	Quantity	Basic UDI-DI	GTIN
9-101-0061	IGH Gene Clonality Assay for ABI Fluorescence Detection	33 Reactions	08100227391010061PN	00850052003142
9-101-0081	IGH Gene Clonality Assay MegaKit for ABI Fluorescence Detection	330 Reactions	08100227391010081PU	00850052003159

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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