



## DECLARATION OF CONFORMITY

**Manufacturer:** **Invivoscribe, Inc.**  
10222 Barnes Canyon Rd. Bldg 1  
San Diego, California 92121  
United States of America

**Authorized Representative:** **Invivoscribe Technologies, SARL**  
c/o Ficorec Domiciliation Services  
132, Boulevard Michelet  
Hall Nord - 5ème étage  
13008 Marseille, FRANCE

**UK Responsible Person:** Gillian Pawlowsky Ltd.  
272 Bath Street  
Glasgow G2 4JR  
Scotland UK

**Family Name:** IdentiClone™

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

Catalog #	Device	Quantity	Basic UDI-DI	GTIN	EMDN Code
9-101-0061	IGH Gene Clonality Assay for ABI Fluorescence Detection	33 Reactions	08100227391010061PN	00850052003142	W010699
9-101-0081	IGH Gene Clonality Assay MegaKit for ABI Fluorescence Detection	330 Reactions	08100227391010081PU	00850052003159	W010699

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.

I, the undersigned, hereby declare that the *in-vitro* diagnostic medical devices specified above conform to the Part IV of the UK Medical Device Regulations 2002, Annex III (as modified by Part III of the Schedule 2A to the UK MDR 2002).

\*Date of Validity: 10 Oct 2023

By: Jason Gerhold

Jason Gerhold  
Global Director of Quality, Regulatory and Clinical Affairs  
Invivoscribe, Inc.  
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San Diego, California 92121  
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\*Originally signed on 05/17/2022, no significant changes have occurred to the product since that date