



## DECLARATION OF CONFORMITY

**Manufacturer:** Invivoscribe Technologies, Inc  
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San Diego, California 92121  
United States of America

**Authorized Representative:** Invivoscribe Technologies, SARL  
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**Family Name:** IdentiClone™

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

Catalog #	Device	Quantity
9-101-0020	IGH Gene Clonality Assay for Gel Detection	33 Reactions
9-101-0061	IGH Gene Clonality Assay for ABI Fluorescence Detection	33 Reactions
9-101-0022	IGH Gene Clonality Assay for Beckman Coulter CE / NAT	33 Reactions
9-101-0040	IGH Gene Clonality Assay MegaKit for Gel Detection	330 Reactions
9-101-0081	IGH Gene Clonality Assay MegaKit for ABI Fluorescence Detection	330 Reactions
9-101-0042	IGH Gene Clonality Assay MegaKit for Beckman Coulter CE / NAT	330 Reactions

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: Nov 2, 2010

By: 

Jeffrey E. Miller, PhD  
CSO and CEO  
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