invivoscribe

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:

LymphoTrack® Dx

Device Trade Name:

IGHV Leader Somatic Hypermutation Assay Kits - MiSeq®

Catalog #	Device	Quantity	Basic UDI-DI	GTIN	EMDN Code
9-121-0059	LymphoTrack® Dx *IGHV* Leader Somatic Hypermutation Assay Kit A – MiSeq®	40 Reactions	08100227391210059QV	00850052003814	W010699
9-121-0069	LymphoTrack® Dx *IGHV* Leader Somatic Hypermutation Assay Panel – MiSeq®	120 Reactions	08100227391210069QY	00850052003821	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 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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USA

*Originally signed on 05/17/2022, no significant changes have occurred to the product since that date