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**: *IGK* Assay Kits – MiSeq

| Catalog # | Device | Quantity | Basic UDI-DI | GTIN | EMDN Code |
|---|---|---|---|---|---|
| 9-122-0009 | LymphoTrack® Dx IGK Assay Kit A – MiSeq® | 40 Reactions | 08100227391220009QR | 00850052003906 | W010699 |
| 9-122-0019 | LymphoTrack® Dx IGK Assay Panel – MiSeq® | 120 Reactions | 08100227391220019QU | 00850052003913 | 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 05/18/2022, no significant changes have occurred to the product since that date