Declaration of Conformity

Manufacturer:

Lab Kinetics LLC,
150 Mustang Dr,
Hutto, Texas 78634
USA

Authorized Representative:

Emergo Europe,
Prinsessegracht 20, 2514 AP,
The Hague,
The Netherlands
SRN NL-AR-000000116

Product Name: Incubating Kinetic Tube Reader

Model/Number: PKF08

Catalogue Number: PKF08-1

Device Classification: Class A (Non-Sterile) (Rule 5b)

Intended Use: The PKF08 provides data, used to analyze human serum samples

Primary UDI-DI: 00860002740003 from GS1

Conformity Assessment Procedure: Annex IV of IVDR REGULATION (EU) 2017/ 746 OF THE EUROPEAN UNION

I, the undersigned, **hereby** declare under the sole responsibility of Lab Kinetics LLC that the above mentioned IVD product meets the provision of the IVDR REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in-vitro diagnostic medical devices, as transposed in the national laws of the Member States and meets the applicable essential requirements of Annex IV, IVDR; and meets the requirements of the EU Directive 2011/65/EU (RoHS) and the directive 2015/863 amendment to Annex II of 2011/65/EU.

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SIGNATURE: Mr. Philip J. Chalmers B.Eng.
CEO, Lab Kinetics, LLC

Hutto, Texas, USA
Place

2022-06-19
Date