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  
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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Hutto, Texas, USA  
2022-06-19

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