

# Declaration of Conformity

**Manufacturer:** Lab Kinetics LLC,  
150 Mustang Dr,  
Hutto, Texas 78634  
USA

**Authorized Representative:** Associates of Cape Cod Europe GmbH  
Opelstrasse 14  
D-64546 Mörfelden-Walldorf  
Germany

**Product Name: Incubating Kinetic Tube Reader**

**Model/Number: PKF08**

**Catalogue Number: PKF08-1**

**Device Classification: general/other IVD**

**Conformity Assessment Procedure: Annex III of IVDD 98/79/EC Council Directive**

I, the undersigned, **hereby** declare under the sole responsibility of Lab Kinetics LLC that the above mentioned IVD product meets the provision of the Council Directive 98/79/EC for *In Vitro* Diagnostic Medical Devices and Directive 98/79/EC as transposed in the national laws of the Member States and meets the applicable essential requirements of Annex III, IVDD.



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

Hutto, Texas, USA  
Place

14/01/2021  
Date