EC Declaration of Conformity

Fluxergy Inc. declares that the products listed below comply with the requirements of the listed directives			
Manufacturer Name/Address:	Fluxergy Inc. 30 Fairbanks, Suite 110 Irvine, CA 92618, USA		
Authorized Representative:	Emergo Europe Prinsessegracht 20 2514 AP The Hague, The Netherlands		
Product Description:	**1. Fluxergy Analyzer**	**CAT #5506-CE**	
	2. Fluxergy Test Kit COVID-19	**CAT #5339-CE (10pk)**	**CAT #6177-CE (100pk)**
	contains Fluxergy Card and Reaction Mix COVID-19:	CAT #5246-CE (10pk) CAT #4155-CE (10pk)	CAT #5527-CE (100pk) CAT #5416-CE (100pk)
Conformity Assessment Route:	Annex III (IVDD 98/79/EC)		
Product Classification	General IVD		
Product Code (GMDN):	1. 62875 - Thermal cycler nucleic acid amplification analyser IVD, point-of-care 2. 64747 - SARS-CoV-2 nucleic acid IVD, kit, nucleic acid technique (NAT)		

and in conformity with the requirements of the following EC directives:

98/79/EC	In Vitro Diagnostic Device Directive
2014/30/EU	EMC Directive
2011/65/EU	RoHS 3 Directive
2012/19/EU	WEEE Directive

The following harmonized standards have been applied:

EN ISO 14971, Medical Devices - Application Of Risk Management To Medical Devices

IEC/EN 61010-1, Safety requirements for electrical equipment for measurement, control, and laboratory use. General requirements

IEC/EN 61010-2-010, Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for laboratory equipment for the heating of materials

IEC/EN 61010-2-081, Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes

IEC/EN 61010-2-101, Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for in vitro diagnostic (IVD) medical equipment

EN 61326-2-6, Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment

IEC/EN 62304, Medical device software — Software life cycle processes

EN ISO 13485, Medical devices — Quality management systems — Requirements for regulatory purposes

EN 13612, Performance evaluation of in vitro diagnostic medical devices

EN ISO 23640, In vitro diagnostic medical devices — Evaluation of stability of in vitro diagnostic reagents

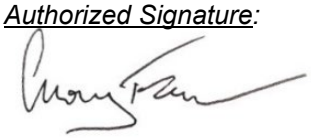
EN ISO 15223-1, Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements

EN ISO 18113-1, In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions and general requirements

EN ISO 18113-2, In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 2: In vitro diagnostic reagents for professional use

EN ISO 18113-3, In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 3: In vitro diagnostic instruments for professional use

This declaration of conformity is issued under the sole responsibility of Fluxergy Inc. and is supported by the Quality System approval to ISO 13485 issued by SAI Global. All supporting documentation is retained at the premises of the manufacturer.

Authorized Signature:	*Date:*	*Name:*	*Title:*
	March 29, 2021	CUONG TRAN	Director of Regulatory Affairs