



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)
	<i>contains Fluxergy Card and Reaction Mix COVID-19:</i>	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 cyler nucleic acid amplification analyser IVD, point-of-care
 2. 64747 - SARS-CoV-2 nucleic acid IVD, kit, nucleic acid technique (NAT)

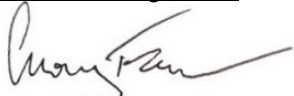
and in conformity with the requirements of the following EC directives:

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:

<p>EN ISO 14971, Medical Devices - Application Of Risk Management To Medical Devices</p> <p>IEC/EN 61010-1, Safety requirements for electrical equipment for measurement, control, and laboratory use. General requirements</p> <p>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</p> <p>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</p> <p>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</p> <p>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</p> <p>IEC/EN 62304, Medical device software — Software life cycle processes</p> <p>EN ISO 13485, Medical devices — Quality management systems — Requirements for regulatory purposes</p>	<p>EN 13612, Performance evaluation of in vitro diagnostic medical devices</p> <p>EN ISO 23640, In vitro diagnostic medical devices — Evaluation of stability of in vitro diagnostic reagents</p> <p>EN ISO 15223-1, Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements</p> <p>EN ISO 18113-1, In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions and general requirements</p> <p>EN ISO 18113-2, In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 2: In vitro diagnostic reagents for professional use</p> <p>EN ISO 18113-3, In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 3: In vitro diagnostic instruments for professional use</p>
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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.

<u>Authorized Signature:</u>	<u>Date:</u>	<u>Name:</u>	<u>Title:</u>
	March 29, 2021	CUONG TRAN	Director of Regulatory Affairs