



## Declaration of Conformity

PRODUCT IDENTIFICATION	
Product Name	Model/Number
MyCare™ Psychiatry Quetiapine Assay Kit	QTP-RGT

MANUFACTURER		
Name of Company	Address	Representative
Saladax Biomedical, Inc.	116 Research Dr Bethlehem, PA, 18015 USA	Amy Orcutt Director of Regulatory and Quality

AUTHORIZED REPRESENTATIVE		
Name of Company	Address	Telephone/Email
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	+31.70.345.8570 - phone LST.AUS.EUAuthRep@ul.com

CONFORMITY ASSESSMENT		
Device Classification	Route to Compliance	Standards Applied
Class: Self-Certified	Annex III of IVDD 98/79/EC Council Directive	ISO 13485      ISO 14971 ISO 13612      ISO 15223-1 ISO 18113-1    EN 1041 ISO 18113-2    EN 13641

**Saladax Biomedical, Inc.** declares that the above mentioned products meet 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.

**COMPANY REPRESENTATIVE:** Salvatore Salamone

**TITLE:** President and CEO

**SIGNATURE:**

A handwritten signature in black ink, appearing to read 'Salvatore Salamone', is written over a horizontal line.

**DATE:** 29 Jan. 2021