

United Kingdom Declaration of Conformity

PRODUCT IDENTIFICATION	
Product Name	Model/Number
Psychiatry Olanzapine Assay Kit	C82915

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

UK PERSON RESPONSIBLE		
Name of Company	Address	Telephone/Email
Emergo Consulting (UK) Limited	c/o Cr360 – UL International Compass House, Vision Park Histon Cambridge CB24 9BZ United Kingdom	Phone: +44(0) 1223 772 671 Email: UKRPvigilance@ul.com

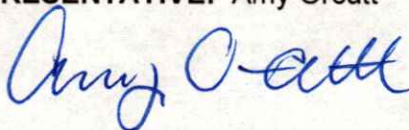
CONFORMITY ASSESSMENT			
Device Classification	Route to Compliance	Standards Applied	
Class: Self-Certified	Annex III of IVDD	ISO 13485:2016	ISO 14971:2019
	98/79/EC Council	ISO 15223-1:2021	EN 13612:2002
	Directive per UK MDR	ISO 18113-1:2009	EN 13641:2002
	2002, Annex III (Section	ISO 18113-2:2009	ISO 780:2015
	1-5)	ISO 20417:2021	

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 United Kingdom, Medical Devices Regulations 2002 (SI 2002 No 618, as amended). This UK-DOC is issued and maintained at the sole responsibility of Saladax Biomedical, Inc.

COMPANY REPRESENTATIVE: Amy Orcutt

TITLE: Director of Regulatory and Quality

SIGNATURE:



DATE: 09 June 2022