

# United Kingdom Declaration of Conformity

PRODUCT IDENTIFICATION	
Product Name	Model/Number
Psychiatry Total Risperidone Assay Kit	C82918

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 98/79/EC Council Directive per UK MDR 2002, Annex III (Section 1-5)	ISO 13485:2016 ISO 15223-1:2021 ISO 18113-1:2009 ISO 18113-2:2009 ISO 20417:2021	ISO 14971:2019 EN 13612:2002 EN 13641:2002 ISO 780:2015

**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