

United Kingdom Declaration of Conformity

PRODUCT IDENTIFICATION

Product Name	Model/Number
Psychiatry Control Kit 2	C82912
Psychiatry Calibrator Kit 2	C82911

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 14971:2019 ISO 15223-1:2021 EN 13612:2002 ISO 18113-1:2009 EN 13641:2002 ISO 18113-2:2009 ISO 780:2015 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