Saladax BIOMEDICAL Distributed by BECKMAN COULTER

Declaration of Conformity

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

MANUFACTURER		
Name of Company	**Address**	**Representative**
Saladax Biomedical, Inc. SRN: US-MF-000007957	116 Research Dr Bethlehem, PA, 18015 USA	Amy Orcutt Director of Regulatory and Quality

AUTHORIZED REPRESENTATIVE		
Name of Company	**Address**	**Telephone/Email**
Emergo Europe SRN: NL-AR-000000116	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 13485:2016 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 Member States. This DOC is issued and maintained at the sole responsibility of Saladax Biomedical, Inc.

COMPANY REPRESENTATIVE: Amy Orcutt **TITLE:** Director of Regulatory and Quality

SIGNATURE: Amy Orcutt **DATE:** May 25, 2022

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FIRST ADDENDUM
Declaration of Conformity

The following addendum to the Declaration of Conformity, effective May 25, 2022, pertains to the product listed in table 1.

Table 1. Product Identification

Product Name	Model/Number
Psychiatry Olanzapine Assay Kit	C82915

The address of the European Authorised Representative (AR), Emergo Europe, has changed, effective 01 February 2023. The new address is provided in table 2.

Table 2. Authorized Representative

Name of Company	Address	Telephone/Email
Emergo Europe SRN: NL-AR-000000116	Westervoortsedijk 60 6827 AT Arnhem The Netherlands	+31.70.345.8570 LST.AUS.EUAuthRep@ul.com

Saladax Biomedical, Inc. declares that based on *MDCG 2022-6 Guidance on Significant Changes Regarding the Transitional Provision Under Article 110(3) of the IVDR* address changes are identified as non-significant:

> *For instance, administrative changes of organisations are considered in principle as non-significant. This includes changes of the manufacturer's name, address or legal form (legal entity remains) or changes of the authorised representative.*

Therefore, this Addendum to the Technical File and DOC does not invalidate the device CE Mark legally applied to the product under Annex III of IVDD 98/79/EC Council Directive.

COMPANY REPRESENTATIVE: John Clay **TITLE:** VP of Regulatory and Quality

SIGNATURE: John Clay **DATE:** 24 March 2023

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