

## Declaration of Conformity

### PRODUCT IDENTIFICATION

| Product Name                   | Model/Number |
|--------------------------------|--------------|
| Psychiatry Clozapine Assay Kit | C82914       |

### MANUFACTURER

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

### AUTHORIZED REPRESENTATIVE

| Name of Company                       | Address  | Telephone/Email                                     |
|---------------------------------------|--|---|
| Emergo Europe<br>SRN: NL-AR-000000116 | Prinsessegracht 20<br>2514 AP The Hague<br>The Netherlands | +31.70.345.8570 - phone<br>LST.AUS.EUAuthRep@ul.com |

### CONFORMITY ASSESSMENT

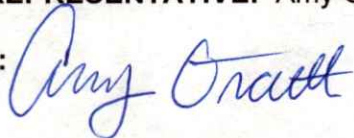
| Device Classification | Route to Compliance                                | Standards Applied  |
|-----------------------|--|--|
| Class: Self-Certified | Annex III of IVDD<br>98/79/EC Council<br>Directive | ISO 13485:2016    ISO 14971:2019<br>ISO 15223-1:2021    EN 13612:2002<br>ISO 18113-1:2009    EN 13641:2002<br>ISO 18113-2:2009    ISO 780:2015<br>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 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:



DATE:

May 25, 2022

# 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 Clozapine Assay Kit | C82914       |

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<br>SRN: NL-AR-000000116 | Westervoortsedijk 60<br>6827 AT Arnhem<br>The Netherlands | +31.70.345.8570<br>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:**



**DATE:**

*24 March 2023*