CEpartner4U

Certificate number: 2020-IVD/CE273

Certificate of CE-Notification

This is to certify that, in accordance with the *In Vitro* Diagnostic Medical Device Directive 98/79/EC, **CEpartner4U BV** agrees to perform all duties and responsibilities as the Authorized Representative for

LuSys Laboratories
10054 Mesa Ridge Court - Suite 118
San Diego CA 92121
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as stipulated and demanded by the aforementioned Directive. The Dutch Competent Authorities have accepted the manufacturer's medical device registrations by CEpartner4U as listed on the product list attached to the manufacturer's Declaration of Conformity:

Device group: Rapid Test	**Notification number: NL-CA002-2020-52272**			
Device name	**Part number**	**Risk class**	**Code: EMDS/GMDN**	**First date of CE-compliance**
COVID-19 IgG/IgM Antibody Test	I-111	Low Risk	15709090	2020-05-18
COVID-19 IgG Antibody Test	I-112	Low Risk	15709090	2020-05-18
COVID-19 IgM Antibody Test	I-113	Low Risk	15709090	2020-05-18
COVID-19 Antigen Test	I-114	Low Risk	15709090	2020-05-18
COVID-19 Combo Test	I-115	Low Risk	15709090	2020-05-18

with Dutch Competent Authorities as a consequently these IVD devices were entered in EUDAMED by Dutch Competent Authorities

The manufacturer has provided CEpartner4U with all necessary documentation including the Intended Use of the devices that meets the requirements of the Directive 98/79/EC, Article 1(b) the devices fall under definitions of '*in vitro* diagnostic medical devices' and, therefore, are medical devices. These devices are not listed on Annex II: list A or list B nor are these devices for self-test and performance evaluation. The conformity assessment of these devices has been according Annex III of the Directive, no involvement of a Notified Body (Self-declaration).

IVD medical devices were registered with Dutch Competent Authorities and consequently these IVD devices were entered in EUDAMED by the Dutch Competent Authorities.

Issue date: 2020-07-16

This Certificate of CE-Notification is valid until May 26, 2022

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