CEpartner4U

Certificate number: 2017-IVD/193

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

CJSC EKOlab

1 Budennogo Str., Elektrogorsk, Moscow region, 142530, Russia

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: Rabbit plasma

IVD devices were registered under number:

Registration number Rabbit plasma: NL-CA002-2017-43242

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

The manufacturer has provided CEpartner4U with all necessary documentation, together with an appropriate Declaration of Conformity that the IVD medical devices fulfil the essential requirements of Directive 98/79/EC.

2017-12-18

Olga Teirlinck
Consultant CEpartner4U BV

Digitally signed by Monastîrschii Viorica
Date: 2022.02.18 14:58:05 EET
Reason: MoldSign Signature
Location: Moldova

CEpartner4U
Esdoornlaan13
3951 DB Maarn NL
tel: +31 (0)343 442 524
www.cepartner4u.nl

DECLARATION OF CONFORMITY

1) **Manufacturer** *(Name, department)*: **CJSC EKOlab**

Address: 1 Budennogo Str., Elektrogorsk, Moscow region, 142530, Russia

2) **European authorized representative: CEpartner4U BV,**

Address: **ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS**;
(on product labels printed as:
CEpartner4U , ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS. www.cepartner4u.com)

3) **Product(s)** *(name, type or model/batch number, etc.)*:

- Rabbit plasma

4) **The product(s) described above is in conformity with:**

Title	Document No.
In vitro Diagnostic Medical Devices Directive	98/79/EC

5) **Additional information** *(conformity procedure, Notified Body, CE certificate, etc.)*:

Conformity assessment procedure for CE marking: *In vitro* Diagnostic Medical Device Directive, Annex III

Registration nr. : pending

Elektrogorsk, Russia; 2017-11-03

(Place & date of issue (yyyy-mm-dd))

V.Y. Borisov, General Director, CJSC EKOlab

(name; function and signature of manufacturer)

Appendix

Date: 2017-11-08

List of devices.

Device name	Type/ model/ref number	Risk class / rule[1]	Code: EMDS/GMDN	First date of CE-compliance
Rabbit plasma		Low risk	15011290/0	2017-11-08

[1] See EDMS codes: http://www.edma-ivd.be/ (products classification)/Preference GMDN code

Certificat

Certificate

N° 2007/28642.5

AFNOR Certification certifies that the management system implemented by:
AFNOR Certification удостоверяет, что система менеджмента организации:

ZAO "EKOlab"
ЗАО «ЭКОлаб»

for the following activities:
для следующих областей деятельности:

DEVELOPMENT, PRODUCTION, STORAGE AND SALE OF MEDICAL DEVICES FOR IN-VITRO DIAGNOSTICS.

РАЗРАБОТКА, ПРОИЗВОДСТВО, ХРАНЕНИЕ И РЕАЛИЗАЦИЯ МЕДИЦИНСКИХ ИЗДЕЛИЙ ДЛЯ IN-VITRO ДИАГНОСТИКИ.

has been assessed and found to meet the requirements of:
проверена и признана соответствующей требованиям стандарта:

ISO 13485:2016

and is developed on the following locations:
и действует на следующих площадках:

142530, RUSSIA, MOSCOW REGION, ELEKTROGORSK CITY, Budennogo str., 1-1A
142530, РОССИЯ, МОСКОВСКАЯ ОБЛАСТЬ, г. ЭЛЕКТРОГОРСК, ул. Буденного, 1-1A

This certificate is valid from (year/month/day)
Данный сертификат действителен с (год/ месяц/ день)
2019-06-28 until *до* **2022-06-27**

ACCRÉDITATION N° 4-0001 PORTÉE DISPONIBLE SUR WWW.COFRAC.FR

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This document is electronically signed. It stands for an electronic original with probationary value.

Franck LEBEUGLE
Managing Director of AFNOR Certification
Генеральный директор AFNOR Certification

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AGENȚIA MEDICAMENTULUI
ȘI DISPOZITIVELOR MEDICALE

GUVERNUL
REPUBLICII MOLDOVA

Nr. hg 02 05577 din 20.12.2021

SANMEDICO S.R.L.
sanmedico.office@gmail.com

Prin prezenta, Agenţia Medicamentului şi Dispozitivelor Medicale (în continuare AMDM), cu privire la înregistrarea dispozitivelor medicale, Vă comunică următoarele:
În temeiul Legii nr. 102 din 09 iunie 2017 (cu privire la dispozitivele medicale) şi procedurii de înregistrare a dispozitivelor medicale, unicul document ce confirmă faptul că dispozitivele medicale au fost înregistrate este Registrul de Stat al dispozitivelor Medicale. Registrul este accesibil pe site-ul oficial al AMDM www.amdm.gov.md (Registrul de Stat al Dispozitivelor Medicale - http://89.32.230.18:8081). Dispozitivele medicale sunt înregistrate pe o perioadă de 5 ani din ziua semnării ordinului.

CONFIRMĂ:

1. Că următoarele dispozitive medicale sunt înregistrate în Registrul de Stat al Dispozitivelor medicale, conform anexei.

Director general **Dragoș GUȚU**

Ex. Levința Alexandru
e-mail: alexandru.levinta@amdm.gov.md

Anexă
la scrisoarea de confirmare AMDM
nr. A07.PS-01.Rg04-188 din 16.07.2018

LISTA
dispozitivelor medicale înregistrate în Republica Moldova

Reprezentantul	Producatorul	Țara	Denumirea dispozitivului medical	Nr. de înreg.
SANMEDICO S.R.L.	ZAO "EKOLAB"	Federatia Rusa	REAGENT PENTRU ANALIZE RABBIT PLASMA	DM000136997