

## DECLARATION OF CONFORMITY

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

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](http://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:**

| <u>Title</u>                                         | <u>Document No.</u> |
|------------------------------------------------------|---------------------|
| <i>In vitro</i> 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 EKOlabor

(name; function and signature of manufacturer)



## Appendix

Date: 2017-11-08

### List of devices.

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

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