



**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.
<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 EKOLab

(name; function and signature of manufacturer)

**Appendix**

Date: 2017-11-08

List of devices.

Device name	Type/ model/ref number	Risk class / rule <sup>1</sup>	Code: EMDS/GMDN	First date of CE- 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