22 Yablonevaja str. Nizhny Novgorod 603093 Russian Federation www.npods.ru E-mail: info@npods.ru

tel/fax Secretary tel/fax Accounting dept. Sales dept. tel/fax

(831) 434-97-70

(831) 434-97-74 (831) 467-82-15



RESEARCH AND PRODUCTION COMPANY

DIAGNOSTIC SYSTEMS

Ne <u>381/09-51</u> of	23.04.2018
Ref.	

Declaration of Conformity

We, RPC "Diagnostic systems", Ltd., 22 Yablonevaya Str., Nizhny Novgorod, 603093, Russia, tel./fax: +7 831 434-86-83

Declare on our own responsibility that

the medical device "DS-EIA-GONADOTROPIN-LH", enzyme immunoassay for the quantitative determination of luteinizing hormone concentration (cat.# RH-152), meets all applicable requirements of Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

Classification of product: self-conformity, according to Directive 98/79/EC.

Name, address and identification number of the Notified body:

mdc medical device certification GmbH (0483), Kriegerstraße 6, 70191 Stuttgart, Germany Tel. +49-(0)711-253597-0, e-mail: mdc@mdc-ce.de.

Conformity assessment procedure:

According to Annex III of the Council Directive 98/79/EC

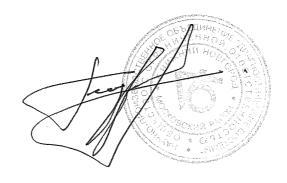
Validity of EC certificates:

No. D1199900032 dated 2018-05-09, valid until 2021-04-17;

Name and address of the authorized representative within EC:

AB Diagnostic Systems GmbH, Sportfliegerstraße 4, 12487 Berlin, Germany Tel. +49 30 54597379, Fax +49 30 54597386 E-Mail: <u>info@ab-ds.de</u>, <u>www.ab-ds.de</u>

General Director, MD, Ph.D.



Anatoly N. Burkov