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RESEARCH AND PRODUCTION COMPANY
DIAGNOSTIC SYSTEMS Ltd.

№ 395/09-51 of 23.07.2018

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-IgE TOTAL", enzyme immunoassay for the quantitative determination of total immunoglobulin E concentration (cat.# ET-151), 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: info@ab-ds.de, www.ab-ds.de

General Director, MD, Ph.D.

Anatoly N. Burkov