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|------------------|---------|-----------------|
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RESEARCH AND PRODUCTION COMPANY  
**DIAGNOSTIC SYSTEMS Ltd.**

No 370/09-51 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-THYROID-TSH", enzyme immunoassay for the quantitative determination of thyrotropin concentration (cat.# TH-351), 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](mailto:info@ab-ds.de), [www.ab-ds.de](http://www.ab-ds.de)

General Director, MD, Ph.D.



Anatoly N. Burkov