

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that

**RPC "DIAGNOSTIC SYSTEMS", Ltd.
22, Yablonevaya Street
603093 Nizhny Novgorod
Russian Federation**

for the scope

**enzyme immunoassays for the detection (confirmation) of
HIV and HBV markers in human blood serum or plasma;
enzyme immunoassays for the determination of
total and free prostate-specific antigen (PSA) in human blood serum;
enzyme immunoassays for the detection of
antibodies against *Toxoplasma gondii*, Rubella virus and
Cytomegalovirus in human blood serum or plasma
(see attachment)**

has introduced and applies a

Quality System

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system
meets all requirements according to

Annex IV – excluding Section 4 and 6 of the Council Directive 98/79/EC

of the European Parliament and of the Council of
27 October 1998 on in vitro diagnostic medical devices.

The surveillance will be held as specified in Annex IV, Section 5.

Valid from	2020-05-05
Valid until	2023-04-17
Registration no.	D1199900042
Report no.	P20-00425-175209
Stuttgart	2020-05-05

Head of Certification Body



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-247.10.05

Attachment of the certificate

No. D1199900042

Date 2020-05-05

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Product category	Product	Class
enzyme immunoassays for the detection (confirmation) of HIV and HBV markers in human blood serum or plasma	DS-EIA-HIV-AGAB-SCREEN (I-1654/1.1, I-1652/1.1, I-1656/1.1) DS-EIA-ANTI-HIV-UNIF (I-153, I-150, I-155) DS-EIA-HBsAg-0.01 (B-1254/1.1, B-1252/1.1, B-1255/1.1, B-1256/1.1, B-231/1.1) DS-EIA-ANTI-HBsAg (B-551/1.1)	List A, Annex II
enzyme immunoassays for the determination of total and free prostate-specific antigen (PSA) in human blood serum	DS-EIA-PSA total (CH-151/1.1) DS-EIA-PSA free (CH-152/1.1)	List B, Annex II
enzyme immunoassays for the detection of antibodies against Toxoplasma gondii, Rubella virus, Cytomegalovirus in human blood serum or plasma	DS-EIA-ANTI-TOXO-G (T-151/1.1) DS-EIA-ANTI-TOXO-M(capture) (T-1153/1.1) DS-EIA-ANTI-RUBELLA-G (RU-151/1.1) DS-EIA-ANTI-RUBELLA-M (RU-153/1.1) DS-EIA-ANTI-CMV-G (CM-151/1.1) DS-EIA-ANTI-CMV-M (CM-153/1.1)	List B, Annex II



Head of Certification Body

