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, HBV and HCV markers in human blood serum or plasma; enzyme immunoassays for the determination of total and free prostate-specific antigen (PSA) in human blood serum (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	2018-05-09
Valid until	2023-04-17
Registration no.	D1199900034
Report no.	P18-00238-114687
Stuttgart	2018-05-09

Head of Certification Body

medical device certification mdc

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

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Attachment of the certificate

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Product category	Product	Class
enzyme immunoassays for the detection (confirmation) of HIV, HBV and HCV 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, B-1252, B-1255, B-1256, B-231) EIA-ANTI-HCV (C-153, C-150, C-155) DS-EIA-HCV-AGAB (C-1952, C-1953, C-1954) DS-EIA-ANTI-HBsAg (B-551)	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

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