

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith grants

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

for the scope

**DS-EIA-HIV-AGAB-SCREEN enzyme immunoassay for
the simultaneous detection of antibodies to human immunodeficiency viruses of
1 and 2 types (HIV-1 and HIV-2), HIV-1 group 0 and HIV-1 p24 antigen in
human blood serum or plasma**

the

EC Design Examination Certificate

The examination of the design of the product by mdc has proven
that the design meets the requirements according to

Annex IV – Section 4 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.

This certificate is only valid in connection with a valid mdc certificate
according to Annex IV – excluding section 4 and 6 for the above mentioned products.

Valid from	2018-06-19
Valid until	2023-06-18
Registration no.	D1199900033
Report no.	P18-00236-114673
Stuttgart	2018-06-19



Head of Certification Body



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