

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-HBsAg-0.01,
Enzyme immunoassay for detection of Hepatitis B surface antigen
DS-EIA-HBsAg-0.01,
Enzyme immunoassay for detection and confirmation of Hepatitis B surface antigen
HBsAg-Confirmatory Test for
confirmation of specificity of Hepatitis B surface antigen detection**

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	2019-04-05
Valid until	2023-11-18
Registration no.	D1199900037
Report no.	P18-00235-114665
Stuttgart	2019-04-05


Head of Certification Body



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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