

# 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-ANTI-HBsAg, enzyme immunoassay for  
qualitative and quantitative detection of antibodies to  
Hepatitis B surface antigen**

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	2019-11-18
Valid until	2024-05-26
Registration no.	D1199900039
Report no.	P19-01254-155441
Stuttgart	2019-11-18



Head of Certification Body

