

# EC Certificate

**mdc medical device certification GmbH**

Notified Body 0483  
herewith grants



**RPC "DIAGNOSTIC SYSTEMS", Ltd.**

**22, Yablonevaya str.  
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	2014-02-07
Valid until	2018-11-18
Registration no.	D1199900019
Report no.	E-D11999_2014-02-07
Stuttgart	2014-02-07

Head of Certification Body

