

# 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 or plasma;**  
**enzyme immunoassay for the determination of  
antibodies against Toxoplasma gondii, Rubella virus, Cytomegalovirus**

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	2013-04-18
Valid until	2018-04-17
Registration no.	4100.21.11/1
Report no.	E 4100.21 / 2013-03-19
Stuttgart	2013-03-19

Head of Certification Body

