EC Certificate

mdc medical device certification GmbH
Notified Body 0483
herewith grants

RESEARCH AND PRODUCTION COMPANY
DIAGNOSTIC SYSTEMS Ltd.

"RPC "Diagnostic Systems"
22, Yablonevaya str.
603093 Nizhniy Novgorod
Russian Federation

for the scope

DS-EIA-ANTI-HBe enzyme immunoassay for the detection of IgG antibodies to e-antigen of Hepatitis B 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	2011-08-04
Valid until	2016-08-04
Registration no.	4100.32.07/0
Report no.	E 4100.32 / 2011-08-04
Stuttgart	2011-08-04

Head of Certification Body

medical device certification mdc

Akkreditiert durch
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-ZE-629.00.17-IVD

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