EC Certificate

mdc medical device certification GmbH
Notified Body 0483
herewith grants

RESEARCH AND PRODUCTION COMPANY
DIAGNOSTIC SYSTEMS Ltd.

RPC "DIAGNOSTIC SYSTEMS", Ltd.
22, Yablonevaya Street
603093 Nizhny Novgorod
Russian Federation

for the scope

DS-EIA-HIV-AG+AB enzyme immunoassay for simultaneous detection of antibodies to human immunodeficiency viruses of 1 and 2 types (HIV-1 and HIV-2), HIV-1 group O and HIV-1 p24 antigen 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	2013-04-18
Valid until	2018-04-17
Registration no.	4100.32.15/0
Report no.	E 4100.32 / 2013-04-18
Stuttgart	2013-04-18

Head of Certification Body

medical device certification mdc

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-247.10.05

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