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-ANTI-HIV-UNIF - Enzyme Immunoassay for the detection of antibodies to human immunodeficiency viruses types 1 and 2 (HIV-1 and HIV-2) and HIV-1 group 0 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 Valid until Registration no. Report no. Stuttgart 2016-12-05 2021-02-11 D1199900031 P16-00254-67309 2016-12-05

Head of Certification Body





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