EC Certificate

mdc medical device certification GmbH

Notified Body 0483 herewith grants

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

for the scope

DS-EIA-ANTI-HBsAg, enzyme immunoassay for qualitative and quantitative detection of antibodies to Hepatitis B surface antigen

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 2022-04-12 2024-11-17 D1199900052 P21-01975-235143 2022-04-12

Head of Certification Body





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