

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith grants

**DiaMex GmbH
Siemensstraße 38
69123 Heidelberg
Germany**

for the scope

**QConnect Controls (antibodies to HIV, HTLV, HCV, HBs,
HBe, HBe as well as HBs Antigen and p24 Antigen)
QConnect SeroNeg REF: SR01000
QConnect Blue REF: SR01011, SR01012, SR01015
QConnect Yellow REF: SR01021, SR01022, SR01025
QConnect Purple REF: SR01031, SR01032, SR01035
QConnect Green REF: SR01041, SR01042, SR01045
QConnect Red REF: SR01051, SR01052, SR01055
QConnect Orange REF: SR01061, SR01062, SR01065
QConnect HIVp24 REF SR01101, SR01103, SR01105
QConnect HIV 2 REF: SR01113, SR01115
QConnect HTLV II REF: SR01143, SR01145
QConnect HEPR REF: SR02013, SR02015**

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	2018-07-16
Valid until	2022-01-03
Registration no.	D1329000019
Report no.	P17-00872-99941
Stuttgart	2018-07-16

Head of Certification Body



Benannt durch/Designated by
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bei Arzneimitteln und
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