

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, HBc, HBe as well as
HBs Antigen, HBe Antigen and p24 Antigen)
(see attachment)**

the

EC Design Examination Certificate

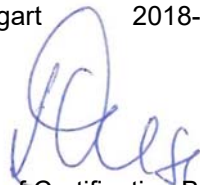
The examination of the design of the product by mdc has proven
that the design meets the requirements according to

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	2018-12-03
Valid until	2022-01-03
Registration no.	D1329000022
Report no.	P17-00875-99956
Stuttgart	2018-12-03



Head of Certification Body



Attachment of the certificate

No. D1329000022

Date 2018-12-03

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Product category	Product	Class
QConnect Controls (antibodies to HIV, HTLV, HCV, HBs, HBc, HBe as well as HBs Antigen, HBe 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 Grey REF: SR01071, SR01072, SR01075 QConnect HIVp24 REF: SR01101, SR01103, SR01105 QConnect HEPR REF: SR02013, SR02015 QConnect HTLV II REF: SR01143, SR01145 QConnect HIV 2 REF: SR01113, SR01115 QConnect HEPA-1 REF: SR02023, SR02025 QConnect HEPA-2 REF: SR02033, SR02035	List A, Annex II



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