

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);

Optitrol 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	2019-11-07
Valid until	2022-01-03
Registration no.	D1329000028
Report no.	P19-00511-144307
Stuttgart	2019-11-07

Head of Certification Body



Attachment of the certificate

No. D1329000028

Date 2019-11-07

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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) Optitrol Controls (antibodies to HIV, HTLV, HCV, HBs, HBc, HBe as well as HBs antigen, HBe antigen and p24 antigen)	QConnect Blue REF: SR01011, SR01012, SR01013, SR01019 QConnect Yellow REF: SR01021, SR01022, SR01023, SR01029 QConnect Purple REF: SR01031, SR01032, SR01033, SR01039 QConnect Green REF: SR01041, SR01042, SR01043, SR01049 QConnect Red REF: SR01051, SR01052, SR01053, SR01059 QConnect Orange REF: SR01061, SR01062, SR01063, SR01069 QConnect Grey REF: SR01071, SR01072, SR01073, SR01079 QConnect SeroNeg REF: SR01000, SR01001, SR01002 QConnect HEPR REF: SR02013, SR02015 QConnect HEPA-1 REF: SR02023, SR02025, SR02027 QConnect HEPA-2 REF: SR02033, SR02035, SR02037 QConnect HIVp24 REF: SR01101, SR01103, SR01105, SR01107 QConnect HIV 2 REF: SR01113, SR01115, SR01117 QConnect HTLV II REF: SR01143, SR01145	List A, Annex II



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QConnect Controls (antibodies to HIV, HTLV, HCV, HBs, HBc, HBe as well as HBs antigen, HBe antigen and p24 antigen) Optitrol Controls (antibodies to HIV, HTLV, HCV, HBs, HBc, HBe as well as HBs antigen, HBe antigen and p24 antigen)	Optitrol Blue REF: SR11011, SR11013, SR11019 Optitrol Yellow REF: SR11021, SR11023, SR11029 Optitrol Purple REF: SR11031, SR11033, SR11039 Optitrol Green REF: SR11041, SR11043, SR11049 Optitrol Red REF: SR11051, SR11053, SR11059 Optitrol Orange REF: SR11061, SR11063, SR11069 Optitrol Grey REF: SR11071, SR11073, SR11079 Optitrol SeroNeg REF: SR11000, SR11001, SR11002 Optitrol HEPR REF: SR12015, SR12017 Optitrol HEPA-1 REF: SR12025, SR12027 Optitrol HEPA-2 REF: SR12035, SR12037 Optitrol HIVp24 REF: SR11101, SR11103, SR11105, SR11107 Optitrol HIV 2 REF: SR11113, SR11115, SR11117 Optitrol HTLV II REF: SR11143, SR11145	List A, Annex II



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