

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith grants

**DiaMex GmbH
Siemensstraße 38
69123 Heidelberg
Germany**

for the scope

**Optitrol NAT: Molecular biological controls for HIV, HBV, HCV
(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	2020-03-23
Valid until	2024-05-26
Registration no.	D1329000029
Report no.	P20-00460-172373
Stuttgart	2020-03-23



Head of Certification Body



Attachment of the certificate

No. D1329000029

Date 2020-03-23

Page 1 of 1

Product category	Product	Class
Optitrol NAT HBV Controls (HBV)	Optitrol NAT HBV Screening, REF: NT01011, NT01012 Optitrol NAT HBV Viral Load, REF: NT01013, NT01014	List A, Annex II
Optitrol NAT HCV Controls (HCV)	Optitrol NAT HCV Screening, REF: NT01021, NT01022 Optitrol NAT HCV Viral Load, REF: NT01023, NT01024	List A, Annex II
Optitrol NAT HIV Controls (HIV-1)	Optitrol NAT HIV Screening, REF: NT01031, NT01032 Optitrol NAT HIV Viral Load, REF: NT01033, NT01034	List A, Annex II
Optitrol NAT Triplex Controls (HIV-1, HBV, HCV)	Optitrol NAT Triplex, REF: NT01041, NT01042	List A, Annex II
Optitrol NAT NEG Controls (HIV-1, HBV, HCV)	Optitrol NAT NEG, REF: NT01051, NT01052	List A, Annex II



Head of Certification Body

