

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith grants

Human

**Gesellschaft für Biochemica und Diagnostica mbH
Max-Planck-Ring 21
65205 Wiesbaden
Germany**

for the scope

**HIV Ag/Ab - ELISA for the detection of antibodies
to human immunodeficiency virus types 1 and 2 (HIV-1, HIV-2),
HIV-1 group O and p24 antigen in human serum and plasma (REF 51215)**

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	2022-02-15
Valid until	2025-05-26
Registration no.	D1030000082
Report no.	P21-01447-214789
Stuttgart	2022-02-15


Head of Certification Body

