

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith grants



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

for the scope

**Anti-HIV 1/2 ELISA for the detection of antibodies to
human immunodeficiency virus types 1 and 2 (HIV-1, HIV-2)
in human serum and plasma**

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	2011-08-31
Valid until	2016-08-30
Registration no.	0063.32.12/0
Report no.	E 0063.32 / 2011-08-31
Stuttgart	2011-08-31

Head of Certification Body



Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
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