

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

HEXAGON HIV (57002P, 57004P) Immunochromatographic rapid test for the qualitative detection of IgM, IgA and IgG antibodies to immune deficiency virus HIV-1 and HIV-2 in human whole blood, serum or 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.

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|------------------|-----------------|
| Valid from | 2014-09-29 |
| Valid until | 2019-06-02 |
| Registration no. | D1030000032 |
| Report no. | P14-00929-22354 |
| Stuttgart | 2014-09-29 |



Head of Certification Body

