

# 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.

Valid from	2019-06-13
Valid until	2024-05-26
Registration no.	D1030000075
Report no.	P18-01308-130152
Stuttgart	2019-06-13



Head of Certification Body



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
[www.zlg.de](http://www.zlg.de)  
ZLG-BS-247.10.05