

# 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**

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	2016-09-02
Valid until	2021-08-25
Registration no.	D1030000048
Report no.	P15-01625-58950
Stuttgart	2016-09-02

  
Head of Certification Body



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